

Christina Pramudji, M.D.

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,) Master File
PELVIC REPAIR SYSTEM) No. 2:12-MD-02327
PRODUCTS LIABILITY) JOSEPH R. GOODWIN
LITIGATION) U.S. DISTRICT JUDGE
<hr/>	
THIS DOCUMENT RELATES TO)
THE FOLLOWING CASES IN WAVE)
1 OF MDL 200:)
JOY ESSMAN)
Case No. 2:12-cv-00277)
)
BARBARA A. HILL)
Case No. 2:12-cv-00806)
)
PAULA KRIZ)
Case No. 2:12-cv-00938)
)
BRENDA RIDDELL) ORAL DEPOSITION OF
Case No. 2:12-cv-00547) CHRISTINA PRAMUDJI, M.D.
)
SHARON CARPENTER) MARCH 23, 2016
Case No. 2:12-cv-00554)
)
MARY JANE OLSEN)
Case No. 2:12-cv-00470)
)
VIRGINIA WHITE)
Case No. 2:12-cv-00958)
)
SANDRA WOLFE)
Case No. 2:12-cv-00335)
)
MARIE SMITH (F/K/A BANKS))
Case No. 2:12-cv-01318)
)
SHERRY FOX)
Case No. 2:12-cv-00878)
)
LOIS DURHAM)
Case No. 2:12-cv-00760)
)

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Page 2		Page 4	
1 ELIZABETH BLYNN WILSON)	Case No. 2:12-cv-01286)	1	A P P E A R A N C E S
2)		2	
3 DAPHNE BARKER)	Case No. 2:12-cv-00899)	3	FOR THE PLAINTIFFS:
4)		4	ANDREW N. FAES, ESQ.
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10 CAREY COLE)	Case No. 2:12-cv-00483)	10	FOR THE DEFENDANTS:
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17)		18	ALSO PRESENT:
18 NANCY JO WILLIAMS)	Case No. 2:12-cv-00511)	19	Ms. Tamara Vinson, Court Reporter
19)		20	
20 MARIA STONE)	Case No. 2:12-cv-00652)	21	
21)		22	
22 TERRI KEY SHIVELY)	Case No. 2:12-cv-00379)	23	
23)		24	
24 CHARLENE LOGAN TAYLOR)	Case No. 2:12-cv-00376)		
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1 ORAL DEPOSITION OF CHRISTINA PRAMUDJI, M.D.		1 INDEX	
2 produced as a witness at the instance of the		2 PAGE	
3 PLAINTIFFS, and duly sworn, was taken in the		3 Appearances.....3	
4 above-styled and numbered cause on the 23rd of March,		4	
5 2016, from 1:20 p.m. to 4:25 p.m., before Tamara		5 CHRISTINA PRAMUDJI, M.D.	
6 Vinson, CSR in and for the State of Texas, reported by		6 Examination by Mr. Faes.....8	
7 machine shorthand, at the Westin-Houston Memorial		7	
8 City, 945 Gessner Road, Houston, Texas, 77024,		8 Signature reserved.....136	
9 pursuant to the Federal Rules of Civil Procedure and		9 Reporter's Certificate.....138	
10 the provisions stated on the record or attached		10	
11 hereto.		11	
12		12	
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1 EXHIBIT INDEX 2 PAGE 3 Exhibit No. 1.....8 4 Notice to Take Deposition of Christina 5 Pramudji, M.D. 6 Exhibit No. 2.....11 7 Expert Report of Christina Pramudji, M.D. 8 9 Exhibit No. 3.....15 10 Christina Pramudji Reliance List in 11 Addition to Materials Referenced in 12 Report - MDL Wave 1 13 Exhibit No. 4.....22 14 Curriculum Vitae 15 16 Exhibit No. 5.....10 17 Placeholder 18 Exhibit No. 6.....22 19 Curriculum Vitae 20 21 Exhibit No. 7.....41 22 Gynecare Prosima 23 Exhibit No. 8.....56 24 USDA UPDATE on Serious Complications 25 Associated with Transvaginal Placement of 26 Surgical Mesh for Pelvic Organ Prolapse: 27 FDA Safety Communication 28 Exhibit No. 9.....66 29 FDA News Release - FDA strengthens 30 requirements for surgical mesh for the 31 transvaginal repair of pelvic organ 32 prolapse to address safety risks	1 with you today that are responsive to those requests? 2 A. Yes. 3 Q. What are those materials that you brought 4 today? 5 A. Well, I brought my CV. I brought all the 6 documents in my possession, including the thumb 7 drives, the company educational literature, the 8 literature in publications, all the documents that I 9 would have used in preparation, the patient medical 10 records, everything that I could -- that I could find, 11 with the exception of some of the materials that were 12 produced in prior cases and have been sent back to 13 Butler Snow. 14 Q. Have you brought any invoices with you today 15 regarding your work on the Wave 1 expert reports or 16 any of the -- 17 A. No. 18 Q. -- case-specific reports? 19 A. No. 20 Q. Okay. What I'm -- have you billed for 21 those -- 22 A. No. 23 Q. -- those reports yet? No, you have not. 24 When do you anticipate billing --
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Page 7
1 CHRISTINA PRAMUDJI, M.D., 2 having been first duly sworn, testified as follows: 3 EXAMINATION 4 QUESTIONS BY MR. FAES: 5 Q. Dr. Pramudji, good afternoon. My name is 6 Andy Faes. I'm here to take your deposition today 7 regarding the Prosima device. Do you understand that? 8 A. Yes. 9 Q. And you understand that you're sworn to tell 10 the truth. Correct? 11 A. Yes. 12 Q. Now, if I ask you -- you've been through this 13 process before, I take it, but if I ask you a 14 question that you don't understand, just let me know 15 and I'll try to rephrase the question. All right? 16 A. Sure. 17 (Exhibit No. 1 marked.) 18 Q. I'm going to hand you what's been marked as 19 Exhibit No. 1 to the deposition, which is the 20 deposition notice. Let me ask you, Dr. Pramudji, have 21 you reviewed that document prior to today? 22 A. Yes. 23 Q. And attached to that notice there's a number 24 of document requests. Have you brought any materials	Page 9
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	1 A. Probably -- 2 Q. -- for those reports? 3 A. Probably in the next few days. 4 Q. Within the next few days? 5 A. Yes. 6 Q. Okay. What I'm going to do is -- I know I'm 7 throwing off the exhibit numbers, but I'm going to 8 mark as Exhibit No. 5 -- 9 A. Uh-huh. 10 Q. -- a placeholder. And if you and William 11 could agree that when those bills become available -- 12 A. Uh-huh. 13 Q. -- for your general reports and your 14 case-specific reports -- 15 A. Uh-huh. 16 Q. -- that are the subject of this notice of 17 deposition, you'll send those to the Court Reporter 18 and they'll substitute those out as Exhibit No. 5. 19 A. Okay. 20 (Exhibit No. 5 marked.) 21 MR. GAGE: And I would say, I don't have 22 an objection to that, except for I do know I have -- 23 Andy, I heard some generalized commentary back and 24 forth between counsel, not you and me, that there was

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<p>1 some dispute -- I can't remember the details of it -- 2 some dispute as to whether or not we had gotten the 3 invoices from Plaintiffs and their experts and we 4 needed to have some meeting of the minds. I'm 5 assuming we're going to ultimately get to a meeting of 6 the minds on that. So I don't have an objection to 7 producing them, but I do know that there is some 8 dispute out there that we're still needing to get some 9 from your experts. And so, you know, that's not a 10 fight you and I need to discuss or deal with today.</p> <p>11 MR. FAES: No. I agree. 12 (Exhibit No. 2 marked.)</p> <p>13 Q. (By Mr. Faes) Doctor, I'm going to hand you 14 what's been marked as Exhibit No. 2.</p> <p>15 A. Uh-huh.</p> <p>16 Q. Can you tell me what that is?</p> <p>17 A. Yes. This is my expert report regarding the 18 Gynemesh, the Prolift and the Prosima.</p> <p>19 Q. Does this report contain each of the opinions 20 that you've reached regarding the Prosima, Prolift and 21 Gynemesh PS?</p> <p>22 A. Yes, these are my opinions.</p> <p>23 Q. Is there any particular reason why you chose 24 to combine your opinions on those three products into</p>	<p>1 the complication rates for the Prosima device are 2 different than the Gynemesh PS flat mesh. Correct? 3 A. Are you talking about the Gynemesh PS being 4 used as a Prolift or just being used as a -- 5 Q. No. I'm talking about the Gynemesh just as a 6 flat mesh. 7 A. Oh, they're -- actually, they're pretty 8 similar. 9 Q. So it's your -- 10 A. I -- I'm sorry. Before I thought you were 11 talking about the Prolift versus the Prosima, which 12 they have slightly different rates. But with the 13 Gynemesh and the Prosima they're pretty similar. 14 Q. So you believe that the complication rates 15 for the Prosima device and the Gynemesh PS flat mesh 16 -- 17 A. Uh-huh. 18 Q. -- are similar? 19 A. Yes. 20 Q. Do you agree that the Prolift device has a 21 different safety and efficacy profile than the 22 Gynemesh PS flat mesh? 23 A. It has a slightly -- slightly different, but 24 it's -- it's not a huge -- not a huge difference.</p>
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<p>1 a single report as opposed to separating them out? 2 A. Well, because the products are made of 3 Gynemesh PS and a lot of the science correlates with 4 -- with all the products, it seemed to make more sense 5 to just combine it.</p> <p>6 Q. Would you agree that the Prosima, for 7 example, has a different safety and efficacy profile 8 than the Gynemesh PS flat mesh?</p> <p>9 A. It does have a different efficacy, yes. But 10 -- but I think a lot of the general -- the general 11 points about the different products come together 12 nicely and the opinions can be held.</p> <p>13 Q. So you've answered my question on efficacy. 14 A. Uh-huh.</p> <p>15 Q. Do you agree that the Prosima has a different 16 safety profile than the Gynemesh PS flat mesh?</p> <p>17 A. It depends on what you're -- what you're 18 talking about. There are some differences, yes.</p> <p>19 Q. You'd agree that the Prosima device has some 20 unique risks that are unique to the Prosima. Correct? 21 A. I don't know if they're unique risks. I'm 22 thinking more about the rates may be different when 23 you compare the products. 24 Q. But as a general principle, we can agree that</p>	<p>1 Q. Well, you'd agree, for example, that the 2 Prolift kit has trocars and the Gynemesh PS flat 3 mesh and the Prosima mesh do not have trocars. 4 Correct? 5 A. That's correct, yes. 6 Q. Would you agree that the trocars used in the 7 Prolift mesh kit can introduce unique risks that are 8 not risks of the Gynemesh PS flat mesh or the Prosima 9 device? 10 A. They -- they can, yes. I don't know that 11 they're really significant looking at the literature, 12 but that is a theory that's out there. 13 MR. FAES: Okay. Object and move to 14 strike after the answer "yes." 15 Q. (By Mr. Faes) Now, in your report, which 16 I've marked as Exhibit 2, you go through various facts 17 and discuss facts. Did you discuss the facts that you 18 were -- you felt were the most important in drawing 19 your opinions in the report? 20 A. Yes. 21 Q. In terms of your decision making in writing 22 the report, why did you choose to cite the articles in 23 your report that you cited? 24 A. Well, I try to cite as much level one</p>

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<p>1 literature as I can, which is going to be randomized 2 controlled trials and review studies where they're, 3 you know, gathering together a lot of large studies 4 because that's the highest level of literature and try 5 to get a good sampling of the highest level studies 6 that there are. 7 (Exhibit No. 3 marked.) 8 Q. Okay. I'm going to hand you what's been 9 marked as Exhibit No. 3 to your deposition. 10 A. Uh-huh. 11 Q. Can you tell me what that is? 12 A. It's the reliance list. 13 Q. Now -- 14 MR. FAES: Do you have something to say, 15 William, before I . . . 16 MR. GAGE: Just don't forget to -- she 17 mentioned an updated resume. I didn't want you to 18 forget to -- 19 MR. FAES: Oh. 20 MR. GAGE: -- mark that as a separate 21 exhibit, which I'm handing to you. I mean, do it 22 after you ask the questions on the reliance list. 23 MR. FAES: Sure. 24 MR. GAGE: I didn't mean to interrupt</p>	<p>1 A. Butler Snow helped me to make the list. 2 Q. Does this list contain all of the materials 3 that you reviewed and relied upon in forming your 4 opinions in this case? 5 A. Yes. 6 Q. You've mentioned that you've brought a number 7 of materials with you. 8 A. Uh-huh. 9 Q. There's flash drives, there's materials 10 stacked in front of you. 11 A. Uh-huh. 12 Q. Is everything -- is there anything that 13 you brought today -- strike that. I'll start over -- 14 A. Uh-huh. 15 Q. -- and ask a new question because you 16 look like you're maybe a little confused. 17 Is there anything that you brought with you 18 today that you've reviewed and relied upon in forming 19 your opinions on the Prolift, Prosima or Gynemesh 20 PS -- 21 A. Uh-huh. 22 Q. -- that is not listed on Exhibit No. 3? 23 A. Not to my knowledge. 24 Q. Now, you've combined your reliance</p>
Page 15	Page 17
<p>1 you. 2 MR. FAES: Well, I already had a 3 different one marked, so . . . 4 MR. GAGE: Yeah. Is that -- well, he'll 5 ask you -- he'll ask you whether you updated that one 6 at the appropriate time. I'm sorry to interrupt. I 7 just didn't want to forget. I handed it to you when I 8 looked down and I saw it in my lap. 9 MR. FAES: I don't see any difference 10 between this and the one I have. Anyway. . . 11 Q. (By Mr. Faes) Now, Dr. Pramudji -- 12 A. Uh-huh. 13 Q. -- Exhibit 3 -- 14 A. Uh-huh. 15 Q. -- is that the reliance list for both your 16 Prosima/Gynemesh PS/Prolift report, as well as your 17 TVT and TVTO general report? 18 A. Yes. 19 Q. And at this time, you haven't issued any 20 general reports on any of the TVT products, other than 21 the TVT retropubic device and the TVTO device. Right? 22 A. That's correct. 23 Q. Now, did you make this list or was it 24 provided for you?</p>	<p>1 list for the -- we'll call them the pelvic organ 2 prolapse products. When I say pelvic organ prolapse 3 products, I'm referring from here on out as the 4 Prolift, the Prosima and the Gynemesh PS. Can we 5 agree to that? 6 A. Yes. 7 Q. So you combined your opinions -- strike that. 8 You've combined your reliance list for your 9 report on the pelvic organ prolapse products and your 10 general report on the TVT and TVTO products. Correct? 11 A. Yes. 12 Q. There's one reliance list for both reports. 13 Correct? 14 A. Yes. 15 Q. In forming your opinions, did you rely on 16 midurethral slings -- strike that. 17 In forming your opinions on the POP products, 18 did you rely on midurethral strings [sic] and the TVT 19 to form any of your opinions regarding the safety and 20 efficacy of the Prolift? 21 MR. GAGE: Object to form. 22 A. Not for the -- not for the major substance of 23 my opinions. I mean, for, you know, peripheral 24 knowledge, I think it helps support the safety of the</p>

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<p>1 mesh, but obviously they're very different products, 2 so you can't draw too many conclusions --</p> <p>3 Q. (By Mr. Faes) Okay. So same --</p> <p>4 A. -- on the general safety of the mesh.</p> <p>5 Q. Sorry. I didn't mean to interrupt you. So 6 same question: Prosima and Gynemesh PS, in forming 7 your opinions, did you rely on midurethral slings and 8 the TVT to form any of your opinions regarding the 9 safety and efficacy of the Gynemesh PS or the Prosima?</p> <p>10 A. I'm sorry. Wasn't that the same question 11 that I just answered?</p> <p>12 Q. You answered it for Prolift the first time.</p> <p>13 A. Oh, okay. Well, it would be the same answer.</p> <p>14 Q. Okay. Thank you. Now, when were you first 15 contacted about being a general expert in this case 16 regarding the Prosima?</p> <p>17 A. Well, the M -- this M -- this big MDL wave 18 was in November.</p> <p>19 Q. Okay.</p> <p>20 A. But there was another Prosima case prior to 21 that, maybe a year, year and a half ago.</p> <p>22 Q. Right. You're referring to the Caviness 23 case --</p> <p>24 A. Right.</p>	<p>1 because it was Texas --</p> <p>2 MR. FAES: Right. And you guys --</p> <p>3 THE WITNESS: -- Federal court.</p> <p>4 MR. FAES: And you guys never do any 5 more than that.</p> <p>6 THE REPORTER: We have to do this one at 7 a time, please.</p> <p>8 MR. FAES: Sorry.</p> <p>9 MR. FAES: Okay. So I'll just ask if 10 the -- that -- if one was created for the Caviness 11 case, a written report, that you provide that to us.</p> <p>12 Q. (By Mr. Faes) How many hours would you 13 -- strike that. I'm going to ask a different 14 question.</p> <p>15 When were you first contacted about being an 16 expert in this case regarding the Gynemesh PS?</p> <p>17 A. When you say "this case," you mean -- what do 18 you mean specifically?</p> <p>19 Q. I mean this Wave 1 general expert report.</p> <p>20 A. This. Oh, okay. So that all just started in 21 November.</p> <p>22 Q. Have you -- do you have an estimate of the 23 number of hours that you've spent preparing this 24 report which is marked as Exhibit 3?</p>
Page 19	Page 21
<p>1 Q. -- where you were asked by Butler Snow to be 2 an expert?</p> <p>3 A. Yes.</p> <p>4 Q. But you didn't prepare a written report 5 in that case. Correct?</p> <p>6 A. I honestly can't recall. I don't know. I 7 can't remember. At this point, I'd have to look back 8 at my records.</p> <p>9 MR. FAES: Okay. And I'd ask if one was 10 -- was created that it be produced to us, but, 11 William, correct me if I'm wrong, I'm pretty sure 12 there wasn't. It was just an expert disclosure. 13 Right?</p> <p>14 MR. GAGE: Andy --</p> <p>15 THE WITNESS: I think --</p> <p>16 MR. GAGE: -- I honestly don't know, but 17 I will tell you, my sense is --</p> <p>18 THE WITNESS: That's right.</p> <p>19 MR. GAGE: -- in Texas State court, I 20 think the rule is we only had to do disclosures and 21 not reports.</p> <p>22 MR. FAES: Yeah.</p> <p>23 MR. GAGE: And I think you're --</p> <p>24 THE WITNESS: Yeah, that's what it --</p>	<p>1 A. Yeah. Probably, I would say -- I would 2 estimate about 50 hours.</p> <p>3 Q. Now, that 50 hours, is that for the entire 4 report for all three of the pelvic organ prolapse 5 products?</p> <p>6 A. Yes.</p> <p>7 Q. How many hours of that 50 would you say you 8 spent actually drafting the report?</p> <p>9 A. Probably about 20.</p> <p>10 Q. And how many of those hours would you say you 11 spent reviewing materials that went into the report?</p> <p>12 A. About 30. A lot of the materials I was 13 already familiar with from previous cases. 14 (Exhibit No. 4 marked.)</p> <p>15 Q. Okay. I'm going to hand you what's been 16 marked as Exhibit 4, which is the -- your CV that was 17 produced to us. And I'm also going to mark as 18 Exhibit 6 the CV that counsel just gave me, which was 19 represented as your updated CV. At first glance, I 20 couldn't tell my difference to it. We'll refer to 21 Exhibit 6 most of the time. 22 (Exhibit No. 6 marked.)</p> <p>23 Q. So if you look at Exhibit No. 6, which has 24 been represented as your current updated CV, there's a</p>

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1 list of publications. Correct?	1 Q. You've never treated -- strike that.
2 A. Correct.	2 You've never published any peer-reviewed
3 Q. Do any of the publications listed in your CV	3 literature in the area of treating mesh complications
4 specifically address the Prosima product?	4 either. Is that correct?
5 A. No.	5 A. That's correct.
6 Q. Do any of the publications listed in your	6 Q. Now, you've used the Prosima in your
7 report specifically address the Gynemesh PS products?	7 practice. Correct?
8 A. No.	8 A. Yes, I have.
9 Q. Do any of the publications in your report	9 Q. And you've implanted about 75 of them. Is
10 specifically address the transvaginal technique for	10 that --
11 the treatment of prolapse?	11 A. That's sounds about right, yes.
12 MR. GAGE: Object to form. Your -- the	12 Q. Can you tell me when you first implanted the
13 -- and I'll object to the form to last two -- the last	13 Prosima device?
14 two questions. You've asked the question: Do any of	14 A. Let's see. It was shortly after it came out,
15 the publications listed in your report. I'm thinking	15 which I believe was in 2008, if I remember correctly.
16 you're meaning to say listed in your CV.	16 So that would have been -- you know -- shortly after
17 MR. FAES: I do mean that, so I'll --	17 it was launched I -- was when when I tried it.
18 thank you, William. I'll re-ask the question.	18 Q. Now, you wrote in your report, I believe,
19 MR. GAGE: Yeah.	19 that the Prosima didn't have a full launch until -- I
20 Q. (By Mr. Faes) Do any of the --	20 can't find it. I believe you wrote in your expert
21 MR. GAGE: Well, she was giving an	21 report that the Prosima device didn't have a full
22 incorrect answer by saying no and so I felt it was	22 launch until later in -- later in 2010. Is that
23 important to... .	23 correct?
24 THE WITNESS: Oh, I knew what -- I knew	24 A. (No response.)
Page 23	Page 25
1 what he meant.	1 Q. It's Page 41 that you said it was not widely
2 MR. FAES: That's the one time when I	2 launched until August of 2010.
3 appreciate the speaking objection, William.	3 MR. GAGE: Object to form.
4 MR. GAGE: Yes.	4 Q. (By Mr. Faes) Broadly launched. And it's
5 Q. (By Mr. Faes) Do any of the -- Dr. Pramudji,	5 top of Page 40. My mistake.
6 do any of the publications listed in your curriculum	6 MR. GAGE: Object to form.
7 vitae specifically address the Gynemesh PS product?	7 A. Oh, yes, that's correct. I got the dates
8 A. No.	8 confused. So it would have been after that.
9 Q. Do any of the publications listed in your	9 Q. (By Mr. Faes) So that -- what you said
10 curriculum vitae specifically address the transvaginal	10 earlier was incorrect, you don't believe --
11 technique for the treatment of pelvic organ prolapse?	11 A. Yeah.
12 A. No.	12 Q. -- that you first implanted it in 2008?
13 Q. Would you agree that the Prosima is an	13 A. That's -- yeah, that's incorrect. I got the
14 alternative surgical treatment -- strike that.	14 dates confused, yeah.
15 Would you agree that the Prosima is an	15 Q. So you believe that you -- and actually, I
16 alternative surgical procedure for the treatment of	16 was going to ask you later about that date on Page 40
17 prolapse as compared to other techniques that are	17 of your report.
18 available to physicians?	18 A. Uh-huh.
19 MR. GAGE: Object to form.	19 Q. Are you sure that's correct, that it was --
20 A. Yes.	20 wasn't widely launched until August of 2010?
21 Q. (By Mr. Faes) You've never published any	21 MR. GAGE: Object to form.
22 peer-reviewed literature in the area of mesh	22 Q. (By Mr. Faes) Do you think it might have
23 complications. Correct?	23 been August of 2009?
24 A. That's correct.	24 A. I would have to -- I'd have to look back at

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<p>1 my references.</p> <p>2 Q. Okay. But, at any rate, you believe you</p> <p>3 didn't begin using the Prosimma device until it was</p> <p>4 officially launched in either 2009 or 2010, whatever</p> <p>5 the date may be, by Ethicon. Correct?</p> <p>6 A. That's correct, yes.</p> <p>7 Q. But you know that it -- that the Prosimma</p> <p>8 device was actually cleared in 2007?</p> <p>9 A. Yes.</p> <p>10 Q. And was available to a limited number</p> <p>11 of physicians who were conducting trials and studies</p> <p>12 on the device. Is that correct?</p> <p>13 A. Yes.</p> <p>14 Q. So you -- you were not, as far as you know,</p> <p>15 one of the people that was involved in conducting a</p> <p>16 clinical trial on the Prosimma or using the Prosimma</p> <p>17 prior to its full launch by Ethicon. Is that right?</p> <p>18 A. That's correct.</p> <p>19 Q. Now, you use Gynemesh PS in your medical</p> <p>20 practice, as well. Is that correct?</p> <p>21 A. I have used it in the past on a few</p> <p>22 occasions.</p> <p>23 Q. How many times would you estimate you've used</p> <p>24 the Gynemesh PS?</p>	<p>1 A. Absolutely.</p> <p>2 Q. What mesh -- meshes do you use if you need a</p> <p>3 flat mesh, for example?</p> <p>4 A. Well, I -- I haven't really used just a flat</p> <p>5 mesh. I've used -- I've used -- I use the Elevate.</p> <p>6 Q. Still?</p> <p>7 A. No.</p> <p>8 Q. When did you stop using the Elevate?</p> <p>9 A. Well, they've -- they've now stopped</p> <p>10 producing it, so . . .</p> <p>11 Q. When did they stop producing it?</p> <p>12 A. I think -- I think they're in the process of</p> <p>13 stopping, but they announced a couple of weeks ago</p> <p>14 that they are not going to produce it anymore.</p> <p>15 Q. How did you learn of that announce many?</p> <p>16 A. Through an e-mail from ASTORA.</p> <p>17 Q. From -- was it from your sales rep or . . .</p> <p>18 A. No. It was from corporate.</p> <p>19 Q. Okay. And did they say when in that e-mail</p> <p>20 that they would officially stop --</p> <p>21 A. Yes --</p> <p>22 Q. -- making it available for sale?</p> <p>23 A. -- but I can't remember the date. I think if</p> <p>24 the hospitals still have it, it could be used, but,</p>
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<p>1 A. The free cut Gynemesh PS, is that what you're</p> <p>2 referring to.</p> <p>3 Q. Yes. Yes, the flat -- the Gynemesh PS, the</p> <p>4 flat mesh.</p> <p>5 A. Maybe a dozen times.</p> <p>6 Q. Do you recall during what time period you've</p> <p>7 used the Gynemesh PS?</p> <p>8 A. Going back to 2002 and then going forward to</p> <p>9 probably 2011.</p> <p>10 Q. So when you used the Gynemesh prior to 2005,</p> <p>11 did you just use it where you would cut portions of it</p> <p>12 to help you in treating prolapse when you were doing</p> <p>13 native tissue repair?</p> <p>14 A. That's correct.</p> <p>15 Q. Okay. And why did you stop using it in 2011?</p> <p>16 A. Because of the environment around that</p> <p>17 transvaginal mesh with the patients being more wary of</p> <p>18 it and feeling reluctant to have mesh implants.</p> <p>19 Q. So you would agree that you moved away from</p> <p>20 using mesh for pelvic organ prolapse repair?</p> <p>21 A. Yes. Not completely, but, yes. The</p> <p>22 environment was not conducive to using it.</p> <p>23 Q. So when you -- do you still use mesh</p> <p>24 occasionally for pelvic organ prolapse repair?</p>	<p>1 you know, I think patients might feel uncomfortable</p> <p>2 with that. So next time that I need a transvaginal</p> <p>3 mesh, I'll probably use the Boston Scientific mesh.</p> <p>4 Q. Which Boston Scientific mesh do you believe</p> <p>5 you'd use?</p> <p>6 A. Well, I think they only have one transvaginal</p> <p>7 kit right now and I can't recall the name of it.</p> <p>8 Q. Is it the Uphold product?</p> <p>9 A. Uphold, yes.</p> <p>10 Q. I got a little sidetracked with the Elevate</p> <p>11 stuff.</p> <p>12 A. Okay.</p> <p>13 Q. So if you need a -- if you needed a -- strike</p> <p>14 that.</p> <p>15 When is the last time that you recall using a</p> <p>16 flat mesh that you cut yourself or inserted in whole</p> <p>17 in a pelvic organ prolapse repair?</p> <p>18 A. So not a kit --</p> <p>19 Q. Right.</p> <p>20 A. -- you mean?</p> <p>21 Q. Right. A flat mesh like the Gynemesh PS.</p> <p>22 A. The last time would probably be in 2011,</p> <p>23 because at that point I only used it to supplement a</p> <p>24 to Total Prolift that had a large apical defect. So,</p>

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<p>1 at that point, I wasn't even using it by itself. I 2 used it in conjunction with the Prolift. I would 3 fashion a greater apical support with the free mesh, 4 if that makes sense. So where the Total Prolift would 5 go across the apex, I would supplement with the 6 Gynemesh. So the last time that I would have used a 7 free cut mesh just to supplement was probably 8 pre-Prolift.</p> <p>9 Q. Okay. If you -- let me ask you this: If you 10 had a patient with a large defect that you didn't feel 11 you could repair using either native tissue or suture 12 repair or a biologic mesh, would you consider using a 13 synthetic mesh?</p> <p>14 A. Yes.</p> <p>15 Q. What synthetic -- what would be your 16 synthetic mesh of choice in that situation?</p> <p>17 A. I don't know. I don't know who -- I don't 18 even know if they still make Gynemesh, because I 19 haven't used it in so long. I don't even know if that 20 product --</p> <p>21 Q. So --</p> <p>22 A. If that product is available, I would use 23 Gynemesh.</p> <p>24 Q. So, sitting here today, you don't know</p>	<p>1 Q. Yes. 2 A. No, I don't know. 3 Q. Do you know what sizes and configurations the 4 Gynemesh PS currently is available in? 5 A. No. 6 Q. You stated earlier that you stopped using the 7 Gynemesh PS, I think, because of the environment? 8 A. Yes. 9 Q. Did you say -- did I get that right? 10 A. That's correct. 11 Q. What do you mean by that? 12 A. Well, when there's, you know, wall-to-wall 13 litigation commercials, patients look askew at mesh 14 procedures. And so they -- they get scared and they 15 want to look at other alternatives. 16 Q. When did you first begin to use a mesh kit 17 for the treatment of prolapse? 18 A. 2005. 19 Q. And what was the first kit that you used? 20 A. The Prolift. 21 Q. And other than that kit, is the only other 22 kit you've used on a -- not counting, like, cadaver 23 labs -- 24 A. Uh-huh.</p>
<p style="text-align: center;">Page 31</p> <p>1 whether or not the Gynemesh PS is still available or 2 not?</p> <p>3 A. I do not know.</p> <p>4 Q. Have you ever used the Prolene Soft product?</p> <p>5 A. I always get the different nomenclatures 6 confused. Is that the same one as Prolift Plus M?</p> <p>7 Q. No, it is not.</p> <p>8 A. Okay. Is that the Vypro?</p> <p>9 Q. No.</p> <p>10 A. Okay. What is the --</p> <p>11 Q. So -- so let me ask you this: Sitting here 12 today, do you know what the Prolene Soft mesh is?</p> <p>13 A. No, I don't.</p> <p>14 Q. Do you know if there is any difference 15 between the Prolene Soft mesh and the Gynemesh PS 16 mesh?</p> <p>17 A. I can't recall right now.</p> <p>18 Q. So if they're identical, you wouldn't know 19 that one way or the other?</p> <p>20 A. I can't recall what Prolene Soft is.</p> <p>21 Q. Okay. So it's probably also fair to say that 22 you don't know if there's a price difference between 23 the Gynemesh PS or the Prolene Soft mesh?</p> <p>24 A. A price difference?</p>	<p style="text-align: center;">Page 33</p> <p>1 Q. -- but in a -- on a live human woman, is the 2 only other kit that you've used the Elevate?</p> <p>3 A. Elevate, the Prosima --</p> <p>4 Q. Oh, yeah, the Prosima and the --</p> <p>5 A. -- and the Uphold.</p> <p>6 Q. You have used the Uphold?</p> <p>7 A. Yes.</p> <p>8 Q. When did you first use that?</p> <p>9 A. I don't recall. It was several years ago.</p> <p>10 Q. And has it -- when's the last time that you 11 used the Uphold kit?</p> <p>12 A. I really have only tried it a couple of times 13 and that was a few years ago.</p> <p>14 Q. Okay. And you've also used -- I think you 15 just forgot to mention it -- you've used the Prolift 16 Plus M --</p> <p>17 A. Yes.</p> <p>18 Q. -- kit before, as well.</p> <p>19 A. Yes.</p> <p>20 Q. Correct?</p> <p>21 A. Uh-huh, that's correct.</p> <p>22 MR. GAGE: Let me just remind you --</p> <p>23 THE WITNESS: Yes.</p> <p>24 MR. GAGE: -- the way the Court Reporter</p>

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<p style="text-align: center;">Page 34</p> <p>1 has to work, Andy -- let Andy really completely fully 2 finish his question --</p> <p>3 THE WITNESS: Uh-huh.</p> <p>4 MR. GAGE: -- before you answer, because 5 I'm reading the transcript here and a lot of times 6 you're answering before Andy is finished. And we want 7 to make it nice and clean for the record, so I may 8 from time to time nudge you on that point.</p> <p>9 MR. FAES: And the Court Reporter 10 appreciates it, too.</p> <p>11 MR. GAGE: Yeah.</p> <p>12 Q. (By Mr. Faes) Now, during the time that you 13 were using the Prosima, did you also continue to do 14 native tissue repairs with sutures?</p> <p>15 A. Yes, I did.</p> <p>16 Q. Did you view the native tissue repairs with 17 sutures as an alternative to the Prosima and vice 18 versa?</p> <p>19 A. Yes.</p> <p>20 Q. And you've also done abdominal 21 sacrocolpopexy. Correct? I tried to say that 22 correct. I don't know if I did or not.</p> <p>23 A. That was close. Yes. I really started doing 24 that primarily, though, after 2011 when the</p>	<p style="text-align: center;">Page 36</p> <p>1 A. Y mesh. They're all Y meshes. 2 Q. But you don't use the Ethicon Artisyn mesh? 3 MR. GAGE: Object. Form. 4 A. I tried it a couple times, but I didn't -- I 5 didn't prefer it. It was harder to work with in 6 surgery than the Restorelle in my hands. 7 Q. (By Mr. Faes) So it would be fair to say 8 that currently when you do abdominal sacrocolpopexy 9 procedure, your mesh of choice is the Coloplast 10 Restorelle?</p> <p>11 A. That's correct. 12 Q. When you consent a patient for a mesh kit, 13 such as the Prosima device, do you -- did you talk to 14 them about the specific manufacturer and compared the 15 kits with them that were available to use or did you 16 just talk about vaginal mesh, in general, and then you 17 chose the kit for that patient?</p> <p>18 MR. GAGE: Object to form. 19 A. I would talk about the vaginal mesh in 20 general and maybe with the Prosima some of the nuances 21 compared to the Prolift, but I -- other than that, I 22 didn't compare it to different kits. I don't think 23 patients would really be able to -- most patients 24 would not be able to fully understand or appreciate</p>
<p style="text-align: center;">Page 35</p> <p>1 transvaginal mesh became controversial. 2 Q. When did you first start to perform that 3 procedure? 4 A. I did a handful prior to 2011, but I really 5 started using it more after 2011. 6 Q. In terms of an alternative treatment for a 7 patient, would you agree that abdominal sacrocolpopexy 8 would be one of the alternatives if, in fact, there 9 were prolapse in the part of a -- in the part of a 10 pelvis that would be appropriate for that treatment? 11 MR. GAGE: Object. Form. 12 A. I don't understand the last part of your 13 question. 14 Q. (By Mr. Faes) You know what, I'll strike 15 that and ask a new one. 16 What meshes have you used for abdominal sacro 17 -- I'll just say ASC. Okay? What meshes have you 18 used for AFC -- ASC? 19 A. I've used the Ethicon product. 20 Q. Okay. 21 A. The Coloplast product, which is called 22 Restorelle, R-E-S-T-O-R-E-L-L-E. And that's what I 23 use currently. And I've also used the AMS product. 24 Q. The Y mesh or . . .</p>	<p style="text-align: center;">Page 37</p> <p>1 the differences between the different kits. 2 Q. (By Mr. Faes) Okay. So that kind of brings 3 -- 4 A. I didn't see much -- I didn't much use for 5 that. 6 Q. Okay. So that kind of brings me to my next 7 question: You -- what's the time period that you 8 performed the Prolift device? From 2005 until it 9 was no longer available in 2012? 10 A. Yes, that's correct. 11 Q. And you were performing the Prosima from 12 either 2009 or 2010, whenever the launch date was, 13 until its discontinuance. Right? 14 A. That's correct. 15 Q. So during the time when you were implanting 16 both Prosima devices and Prolift devices, how did you 17 decide which kit to use for which patient? 18 A. The Prosima is best suited for a grade 2 or 3 19 cystocele or rectocele without loss of apical support. 20 If they needed more apical support or they had other 21 factors that I thought they needed more support, then 22 I would do the Prolift. 23 Q. So is it fair to say that the Prosima was 24 your device of choice for a patient that had a grade 2</p>

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<p>1 or 3 rectocele or cystocele without loss of apical 2 support?</p> <p>3 A. Yes.</p> <p>4 Q. And your -- was your Prolift your device of 5 choice for all other patients or was there a specific 6 subset of patients that that was your device of choice 7 for?</p> <p>8 A. That was definitely my device of choice for 9 the more severe prolapse patients, grade 4s or some 10 grade 3s, as well, just depending on -- all grade 3s 11 are not the same. They can have different angles and 12 different areas that need support and some of those 13 would get a Prolift, as well.</p> <p>14 Q. Now, like the Prosima device, the Elevate 15 does not have trocar passes. Is that correct?</p> <p>16 A. That's correct.</p> <p>17 Q. One significant difference between -- strike 18 that.</p> <p>19 The fact that there were no external trocar 20 passes with the Elevate or the Prosima, did you see 21 that as a potential benefit from a safety perspective 22 as compared to the Prolift?</p> <p>23 A. Yes, I did. You -- you do avoid some 24 bleeding that could occur with a trocar pass. I</p>	<p>1 can look at it. 2 (Break.)</p> <p>3 Q. (By Mr. Faes) Dr. Pramudji, we're back on 4 the record after a short break. Are you ready to 5 proceed?</p> <p>6 A. Yes. 7 (Exhibit No. 7 marked.)</p> <p>8 Q. Before I -- before the break, I had asked you 9 whether or not the Prosima IFU states that the device 10 is indicated for grade 2 or 3 rectocele or cystocele 11 and I handed you what's been marked as Exhibit No. 7 12 to your deposition, which is the 2010 Prosima IFU. 13 Are you -- have you reviewed that document and are you 14 prepared to answer the question?</p> <p>15 A. Yes. I do not see in there where it says 16 that it's indicated for that.</p> <p>17 Q. Had she --</p> <p>18 MR. GAGE: Hang on just a second. Okay. 19 Go ahead.</p> <p>20 Q. (By Mr. Faes) But you did mention that you 21 believe that it was -- that information was contained 22 in professional education materials?</p> <p>23 A. Yes. 24 Q. Let me ask you this: Do you know if Ethicon</p>
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<p>1 didn't have any other complications with the trocar 2 passes than bleeding at times, but for that reason it 3 would have a slightly -- a slight advantage to the 4 Prosima.</p> <p>5 Q. Now, you talked a little bit about -- a 6 minute ago about the Prosima device being best for 7 grade 2 or 3 defects. Is that correct?</p> <p>8 A. Yes.</p> <p>9 Q. Is there anything, as you sit here today, 10 that you know of in the IFU that tells physicians that 11 the device is best for those two grades of prolapse?</p> <p>12 A. I believe it does state that in the IFU and I 13 know that that is what we taught in the prof ed, as 14 well.</p> <p>15 Q. So you believe it states in the Prolift IFU 16 that it is only indicated for grade 2 or 3 defects?</p> <p>17 MR. GAGE: Object. Form.</p> <p>18 A. I know it's in some of the literature that 19 the company put out. I'd have to look and see if it's 20 in the IFU that I'm picturing in my head right now. 21 Can I look at it?</p> <p>22 Q. (By Mr. Faes) Yeah.</p> <p>23 MR. FAES: Do you want to go off the 24 record for just a second? I need some water and she</p>	<p>1 keeps track of who those professional materials go to? 2 A. I have no idea. 3 Q. You would agree that the IFU, which is 4 Exhibit No. 7 in front of you, is required by law to 5 be in every Prosima product that is sold to 6 physicians. Is that correct?</p> <p>7 A. Correct. 8 Q. So we can ensure -- strike that.</p> <p>9 By contrast, the professional education 10 materials provided by Ethicon are not in every box of 11 the product that goes out to physicians. Is that 12 correct?</p> <p>13 A. Of course not.</p> <p>14 Q. Doctor, do you know the clearance date for 15 the Gynemesh PS flat mesh product?</p> <p>16 A. I think it goes back to 2002.</p> <p>17 Q. And do you know when the Gynemesh PS product 18 was first launched in the United States?</p> <p>19 A. No, I don't.</p> <p>20 Q. And I'll take it, since you don't know what 21 the Prolene Soft product is, you don't know what the 22 clearance date is for that product either?</p> <p>23 A. Correct. 24 Q. And you don't know when the Prolene Soft</p>

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<p>1 product was first available for use by physicians in 2 the United States?</p> <p>3 A. That's right.</p> <p>4 Q. Do you know the clearance date for the 5 Prosimma product? I think we talked about this a 6 little earlier.</p> <p>7 A. I think it was around 2008.</p> <p>8 Q. But you don't know any more specific than 9 that --</p> <p>10 A. No.</p> <p>11 Q. -- sitting here today? Do you recall if you 12 -- if you listed that clearance date for either the 13 Gynemesh PS or the Prosimma product in your report?</p> <p>14 A. I think I did. I can -- I'd have to look and 15 see exactly where I put it in here.</p> <p>16 Q. Okay. I don't -- I don't want to take the 17 time right now, but we'll just -- we'll just have your 18 answer stand that you believe it's in there.</p> <p>19 Let me ask you this, Doctor: Would you -- 20 have you ever used a medical device for something that 21 it was not indicated for?</p> <p>22 A. No.</p> <p>23 Q. Is that something you would consider doing, 24 is using a medical device for something off label or</p>	<p>1 transvaginal use?</p> <p>2 A. Yes, it is.</p> <p>3 Q. So you believe, as you sit here today, that 4 the Gynemesh PS mesh is indicated for transvaginal 5 use?</p> <p>6 A. Yes.</p> <p>7 Q. Do you recall sitting -- as you sit here 8 today, if you've reviewed the 2013 Gynemesh PS flat 9 mesh IFU?</p> <p>10 A. I'm sure I have, but I'd have to refresh my 11 memory on that.</p> <p>12 Q. Okay. Do you recall, as you sit here today, 13 if you've reviewed the 2015 Gynemesh flat mesh IFU 14 that's available on Ethicon's website?</p> <p>15 A. I'm sure I have, but I'd have to review 16 specifics.</p> <p>17 Q. Do you agree with the FDA's viewpoint that 18 there is a need for more rigorous studies regarding 19 the safety and efficacy of mesh kits?</p> <p>20 MR. GAGE: Object to form.</p> <p>21 A. No, I disagree with them, because I think 22 that we have a very strong body of data showing that 23 the mesh kits are safe and effective.</p> <p>24 Q. (By Mr. Faes) Have you ever seen the 522</p>
<p style="text-align: center;">Page 43</p> <p>1 something that was not specifically in its indications 2 for use?</p> <p>3 A. Absolutely. As a trained surgeon, I use my 4 professional judgment and sometimes there are 5 situations where you use things off label, medications 6 or potentially, devices. I haven't used a device off 7 label that I can recall. I have used a medication off 8 label and discussed that with the patient, but that's 9 within the prerogative of the physician to use their 10 judgment.</p> <p>11 Q. And I take it -- you understand that surgical 12 mesh is a medical device. Correct?</p> <p>13 A. Yes.</p> <p>14 Q. So you've never used a surgical mesh off 15 label in your -- how many years have you been 16 practicing?</p> <p>17 A. Fifteen years.</p> <p>18 Q. You've never used a -- so I'll restart the 19 question: You've never used a surgical mesh off label 20 in your 15 years of practice that you can recall. 21 Correct?</p> <p>22 A. That's correct.</p> <p>23 Q. Do you know, sitting here today, whether or 24 not the Gynemesh PS flat mesh is indicated for</p>	<p style="text-align: center;">Page 45</p> <p>1 order that was issued by the FDA with regard to the 2 Prosimma?</p> <p>3 A. I'm sure that I have at some point.</p> <p>4 Q. Do you recall, sitting here today, what it 5 said?</p> <p>6 A. I can't recall.</p> <p>7 Q. Have you seen Ethicon's response to the 522 8 order on the Prosimma?</p> <p>9 A. I'm sure that I have, but I couldn't -- I 10 couldn't recite it to you.</p> <p>11 Q. Do you recall, as you sit here today, if in 12 response to Ethicon's -- strike that.</p> <p>13 Do you recall, as you sit here today, if in 14 response to the FDA's 522 on the Prosimma, Ethicon 15 tried to get the FDA to accept studies that it had 16 already done on the Prosimma in lieu of a 522 study?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 A. I'm not sure if I know about that or not. I 19 don't recall.</p> <p>20 Q. (By Mr. Faes) Has anyone ever told you why 21 the Prosimma was removed from the market?</p> <p>22 MR. GAGE: Object to form.</p> <p>23 A. Not that I recall.</p> <p>24 Q. (By Mr. Faes) Do you have an understanding,</p>

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<p>1 as you sit here today, of why the Prosima was removed 2 from the market?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 A. My understanding is that it was a calculation 5 of being able to sell the product and having the 6 resources to do the research that was required for the 7 522. That was my understanding. I can't recall who 8 told me that.</p> <p>9 Q. (By Mr. Faes) Let me ask you this: Do you 10 intend to offer any opinions in this case about why 11 the Prosima was removed from the market?</p> <p>12 MR. GAGE: Object to form.</p> <p>13 A. I am not sure.</p> <p>14 Q. (By Mr. Faes) Would you agree that from the 15 time that the Ethicon did a full launch of the Prosima 16 product until the time they stopped making it and it 17 was no longer available, it was less than three years?</p> <p>18 A. That's correct.</p> <p>19 Q. Do you know how many Prosima devices Ethicon 20 sold during that time?</p> <p>21 A. No, I don't.</p> <p>22 Q. Do you recall specifically how you found 23 out that the Prosima device was no longer going to 24 be available for sale?</p>	<p>1 stopped selling the product? 2 A. Yes, they did.</p> <p>3 Q. Do you know what they did with those 4 products?</p> <p>5 A. They kept them so that I could use them.</p> <p>6 Q. So you used -- continued to use the Prosima 7 device after the announcement was made that it was no 8 longer going to be available?</p> <p>9 A. Yes.</p> <p>10 Q. How many Prosima devices did you use -- 11 A. I don't recall.</p> <p>12 Q. -- during that time period?</p> <p>13 A. I don't know.</p> <p>14 Q. Do you recall when the last Prosima device 15 you placed was?</p> <p>16 A. No, I don't remember.</p> <p>17 Q. Do you know what the shelf life of the 18 Prosima product is?</p> <p>19 A. No.</p> <p>20 Q. Is it your usual practice to check the 21 expiration date before you implant the product -- 22 A. Absolutely.</p> <p>23 Q. -- in a person?</p> <p>24 A. Sorry. Sorry to interrupt. Yes, absolutely.</p>
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<p>1 A. No, I don't recall.</p> <p>2 Q. Do you recall the month or the year when that 3 occurred?</p> <p>4 A. No.</p> <p>5 Q. Do you recall if you had, like, a warning 6 period -- was -- strike that.</p> <p>7 Was there a time between when you were 8 told that the Prosima was going to be -- was no 9 longer going to be available for sale and when it 10 was actually not available?</p> <p>11 A. Yes.</p> <p>12 Q. Do you recall what hospitals you worked at 13 during that time period when -- between when Prosima 14 -- the announcement on Prosima was first made that it 15 was no longer going to be sold and when it was 16 ultimately no longer available?</p> <p>17 A. Yes.</p> <p>18 Q. Which hospitals were those?</p> <p>19 A. Memorial Hermann, Memorial City.</p> <p>20 Q. Okay.</p> <p>21 A. And Memorial Hermann Katy and St. Catherine's 22 Hospital.</p> <p>23 Q. Do you know if any of those hospitals still 24 had Prosima devices on their shelves after Ethicon</p>	<p>1 Q. And to your knowledge, you've never implanted 2 a product that was past the expiration date. Is that 3 correct?</p> <p>4 A. Not to my knowledge.</p> <p>5 Q. Did you ask the hospital to buy up or 6 stockpile any Prosima devices before it was no longer 7 available when the announcement was made?</p> <p>8 A. No, I didn't ask them to do that. I just 9 felt like I would use what they already had on hand.</p> <p>10 Q. You didn't do any kind of projection of, I 11 think that -- you know -- I anticipate using this many 12 products a month and the shelf life is X number of 13 years, so I'll need this many products, you didn't do 14 that analysis?</p> <p>15 A. No.</p> <p>16 Q. Same question on the Prolift: Do you 17 know if any of the hospitals had that device on its 18 shelves after Ethicon stopped selling the product?</p> <p>19 A. Yes, they did, and I continued to use it.</p> <p>20 Q. And you used it until they ran out?</p> <p>21 A. That's correct.</p> <p>22 Q. And same question on the Prolift: Did you 23 ask any of the hospitals to buy up extra Prolift while 24 it was available --</p>

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<p>1 A. No.</p> <p>2 Q. -- obviously keeping in mind that there's 3 an expiration date on the product and you would need 4 to use it before it expired?</p> <p>5 A. No, I didn't go to that extent.</p> <p>6 Q. What about the Prolift Plus M device?</p> <p>7 A. Same story.</p> <p>8 Q. Okay. So you did continue to use the Prolift 9 Plus M device up until the time it was no longer 10 available?</p> <p>11 A. That's correct.</p> <p>12 Q. We talked a little bit about the selection 13 criteria you used for the Prosima versus the Prolift 14 device. What was your selection criteria for patients 15 on the Prolift Plus M device? What kind of patients 16 did you put that into?</p> <p>17 A. Well, once the Prolift Plus M became 18 available and I felt -- I saw result -- good results 19 in my own patients, I started to transition my Prolift 20 patients to Prolift Plus M patients. And so I began 21 to use it more -- much more frequently than the 22 Prolift. And it would have been basically the same 23 patients with the more severe prolapse or loss of 24 apical support.</p>	<p>1 A. Absolutely. They're great products.</p> <p>2 Q. Do you believe the Prosima device is still 3 cleared by the FDA today?</p> <p>4 A. From a regulatory perspective, I'm not sure. 5 I don't know.</p> <p>6 Q. If it were not cleared, would you still 7 consider implanting the Prosima in a patient?</p> <p>8 MR. GAGE: Object to form.</p> <p>9 A. You know, it worked so great in -- with my 10 patients that I probably would consider it, because 11 looking at the data and with my own experience, I 12 think it's proven to be very effective and safe and I 13 feel very comfortable with it.</p> <p>14 Q. (By Mr. Faes) So do you believe a physician 15 would be within the standard of care if he knowingly 16 implanted a medical device that was not currently cleared 17 or approved by the FDA?</p> <p>18 MR. GAGE: Object to form.</p> <p>19 A. In certain situations, yes. Because our 20 knowledge as physicians allows us the leeway to use 21 things off label.</p> <p>22 Q. (By Mr. Faes) I'm not talking about things 23 that aren't indicated. I'm talking about a device 24 that is no longer cleared or approved by the FDA.</p>
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<p>1 Q. For the Prolift Plus M?</p> <p>2 A. Correct.</p> <p>3 Q. Did -- was there a time that the Prolift Plus 4 M device became your device of choice over the 5 Prolift?</p> <p>6 A. Yes, for a while it was.</p> <p>7 Q. Do you recall about what time period that was 8 when that occurred?</p> <p>9 A. No, I can't remember.</p> <p>10 Q. You said that you waited to switch over until 11 you saw good results in your own patients. Did you do 12 -- do you mean you implanted it in the patients and 13 then waited to see what happened or are you referring 14 to other physicians in your group?</p> <p>15 A. In my own patients --</p> <p>16 Q. Okay.</p> <p>17 A. -- where I could examine them myself and see, 18 see how well it worked.</p> <p>19 Q. If you were able to find a Prosima or a 20 Prolift device today that was not already expired, 21 would you consider implanting it in a patient?</p> <p>22 A. Absolutely.</p> <p>23 Q. Do you believe it's within the standard of 24 care to continue to implant those devices today?</p>	<p>1 A. Uh-huh.</p> <p>2 MR. GAGE: Object to form.</p> <p>3 Q. (By Mr. Faes) Do you understand that?</p> <p>4 A. I see the distinction that you're talking 5 about. I think strictly legally there could be some 6 -- some problems if you implant something that's not 7 FDA approved, but whether that's outside the standard 8 of care, I think -- I think it could still be within 9 the standard of care.</p> <p>10 Q. Backtracking a little bit to the Gynemesh PS 11 flat mesh product, have you ever seen the 522 order 12 that was issued by the FDA with regard to that 13 product?</p> <p>14 A. I believe I have.</p> <p>15 Q. Do you recall, sitting here, what it said?</p> <p>16 A. No, I don't recall.</p> <p>17 Q. Do you know what Ethicon did in response to 18 the 522 order on the Gynemesh PS flat mesh?</p> <p>19 A. No, I don't.</p> <p>20 Q. Have you ever used the standard, traditional 21 Prolene mesh in your medical practice?</p> <p>22 A. What do you mean by standard, traditional 23 Prolene mesh?</p> <p>24 Q. I'm talking about the standard mesh that's</p>

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<p>1 for hernia repair, not Prolene Soft, not Gynemesh. 2 A. No. 3 Q. Standard traditional Prolene mesh. 4 A. No, I have not. 5 Q. Is that a mesh that you would consider using 6 in your practice? 7 A. I don't know. I'm not familiar with it. 8 Q. Let me ask you this: Do you believe it would 9 be a reasonable decision for a doctor to stop using 10 the Prosima device following the July 2011 FDA public 11 health notification? 12 A. Sure. 13 Q. The same question: Do you believe it would 14 be a reasonable decision for a doctor to stop using 15 the Prosima -- strike that. 16 Do you believe it would be a reasonable 17 decision for a doctor to stop using the Prolift or 18 Prolift Plus M device following the July 2011 FDA 19 public health notification? 20 A. If they're uncomfortable with it, that's 21 their prerogative. 22 Q. Would you agree that surgical complications 23 associated with surgical mesh for transvaginal repair 24 of pelvic organ prolapse are not rare?</p>	<p>1 Is that correct? 2 A. Yes, that's correct. 3 Q. Let me ask you this: When you consulted 4 patients after this public health notification was 5 issued, did you talk to them about this notice? 6 A. Absolutely. 7 Q. Did you tell your patients that you disagreed 8 with the public health notification, that you 9 disagreed with the FDA that the complications were not 10 rare? 11 A. Yes, I did, because in my hands and the 12 literature, they are rare. 13 Q. Do you believe that a physician, when they -- 14 a physician who consents is -- strike that. 15 If a physician consents his patients for a 16 pelvic organ prolapse kit procedure and tells that 17 patient that serious complications associated with 18 surgical mesh are rare, do you believe that that 19 physician has appropriately consented the patient? 20 MR. GAGE: Object to form. 21 A. Yes. 22 Q. (By Mr. Faes) Do you agree or disagree that 23 there is no evidence that transvaginal mesh repair 24 with mesh provides any added benefit compared to</p>
<p style="text-align: center;">Page 55</p> <p>1 A. How are you defining "rare"? Or what do you 2 mean by "rare"? Can you clarify that? 3 Q. Well, you're a physician. How do you 4 understand the word "rare" when it relates to 5 complications? 6 A. In my opinion, and looking at the literature 7 and with my own experience, I think that the surgical 8 complications are rare, meaning that they're less than 9 ten percent. 10 (Exhibit No. 8 marked.) 11 Q. I'm going to hand you what's been marked as 12 Exhibit No. 8 to your deposition. This is the 2011 13 public health notification. 14 A. Uh-huh. 15 Q. If I could have you turn to the second page. 16 A. Uh-huh. 17 Q. I'm just going to read the -- one, two, 18 three, four -- fifth paragraph down. It says: The 19 FDA is issuing this update to inform you that serious 20 complications associated with surgical mesh for 21 transvaginal repair of POP are not rare. 22 Do you see that? 23 A. Yes. 24 Q. So you disagree with the FDA in this regard.</p>	<p style="text-align: center;">Page 57</p> <p>1 traditional surgery without mesh? 2 A. I disagree, because I think the literature 3 bears it out, but the transvaginal mesh repair is more 4 effective than traditional repair. There's multiple 5 studies that reinforce that. 6 Q. And you know -- 7 A. And I saw that in my own experience. 8 Q. And if you turn to Page 3, you see that that 9 statement is contained within the public health 10 notification, as well. 11 A. (No response.) 12 Q. It's the third bullet point. I'll read it 13 again for you. There is no evidence that transvaginal 14 repair to support the top of the vagina, parentheses, 15 (apical repair or back wall of the vagina), 16 parentheses, posterior repair with mesh provides any 17 added benefit compared to traditional surgery without 18 mesh. 19 Do you see that? 20 A. Yes, I do. 21 Q. And you disagree with that statement from the 22 FDA? 23 A. When you narrow in on the posterior wall, it 24 is not as much of a benefit as it is on the anterior</p>

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<p>1 wall, which is what I was referring to previously. 2 Q. So I'm not sure if I got an answer to my 3 question. Are you saying you agree with this 4 statement from the FDA or disagree with it or you 5 can't answer? 6 A. I would agree with that bullet point -- 7 Q. When you -- 8 A. -- about the posterior wall. 9 Q. When you consented patients for pelvic organ 10 prolapse procedures after July of 2013 -- 11 A. Uh-huh. 12 Q. -- did you tell them that there was no 13 evidence that using mesh provides any added benefit as 14 compared to traditional surgery without a mesh? 15 MR. GAGE: Object to form. 16 A. What I told patients -- we're speaking of a 17 posterior repair right now. And what I told patients 18 is that there is a slight benefit with the mesh and 19 there is definitely a benefit with decreased pain with 20 the posterior mesh versus a traditional posterior 21 plication repair. Does that answer your question? 22 Q. (By Mr. Faes) Yes. Do you agree that mesh 23 used in transvaginal pelvic organ prolapse repair 24 introduces risks not present in traditional non-mesh</p>	<p>1 20th, 2008 public health notification. 2 So at least according to this, both the FDA 3 and the medical literature believed that mesh 4 contraction or shrinkage does exist. Is that correct? 5 MR. GAGE: Object to form. 6 A. Yes, they do believe that, but I respectfully 7 disagree, because the mesh does not contract. It's 8 the scar tissue around it. And you can see wound 9 contraction and vaginal shortening, tightening, pain 10 with any pelvic floor correction. 11 Q. (By Mr. Faes) So you would disagree with 12 both the FDA and the medical literature that mesh 13 can contract or shrink? 14 MR. GAGE: Object to form. 15 A. Yes, the mesh does not contract or shrink. 16 The wound and the scarring is what contracts and 17 shrinks. The mesh, itself, does not. 18 Q. (By Mr. Faes) When the wound or scar 19 contracts and shrinks -- 20 A. Uh-huh. 21 Q. -- if the mesh is encapsulated -- 22 A. Uh-huh. 23 Q. -- can the mesh shrink, as well, along with 24 the wound or scar tissue?</p>
<p style="text-align: center;">Page 59</p> <p>1 surgery for pelvic organ prolapse repair? 2 A. The only additional risk that it introduces 3 is a mesh exposure. 4 Q. So was my -- the answer to my question, yes, 5 you agree with that statement? 6 A. (No response.) 7 Q. Do you want me to read the question again? 8 MR. GAGE: No. She can look at it here. 9 A. No. It only introduces that one risk. All 10 the other risks are going to be potential with any 11 pelvic floor surgery. 12 Q. (By Mr. Faes) So is it your testimony that 13 mesh contraction is a risk of any other pelvic 14 surgery? 15 A. Wound contraction is. Mesh doesn't contract. 16 The wound contracts and the scarring contracts. 17 Q. You don't believe that mesh contracts? 18 A. No. The wound and the scar contract. 19 Q. If you go down to the second paragraph below 20 the bullet point it says: Mesh contraction, 21 parenthesis, (shrinkage) is a previously unidentified 22 risk of transvaginal POP repair with mesh that has 23 been reported in the scientific literature in an 24 adverse event reports to the FDA since the October</p>	<p style="text-align: center;">Page 61</p> <p>1 A. I mean, it's a matter of semantics. The 2 mesh, itself, is not shrinking or contracting. If you 3 take it out, it's going to be the same Prolene caliber 4 fibers. They're not going to be shrunken. 5 Q. There not going to be shrunken or deformed as 6 the wound or the scar tissue which completely 7 surrounds it contracts? 8 A. The pores will be -- the pores of the mesh 9 maybe shrunken or deformed and pulled together by the 10 scar tissue, but the Prolene, itself, is not shrunken. 11 Q. Do you degree -- strike that. 12 Do you agree or disagree that mesh placed 13 abdominally for pelvic organ prolapse repair results 14 in lower rates of mesh complications compared to 15 transvaginal pelvic organ prolapse surgery with mesh? 16 A. Actually, the mesh erosion rates are similar 17 with the transabdominal and the transvaginally placed 18 mesh looking at the sacrocolpopexy studies. They have 19 similar rates. 20 Q. So if you turn to Page 4 of exhibit -- the 21 exhibit that I just handed you. 22 A. (Complying.) 23 Q. You go under the bullet point: Consider 24 these factors before placing surgical mesh. The last</p>

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<p>1 bullet point you see, it reads: Mesh placed 2 abdominally for pelvic organ prolapse repair may 3 result in lower rates of mesh complications compared 4 to transvaginal pelvic organ prolapse surgery with 5 mesh.</p> <p>6 Is it fair to say that you disagree with the 7 FDA on this statement?</p> <p>8 A. Well, it says it may result. They're not 9 saying it does result in lower rates. And I think, if 10 we look at the literature, we can see they're very 11 similar rates.</p> <p>12 Q. So you -- does that mean you agree with the 13 statement from the FDA that it may result in lower 14 rates of mesh complications compared to transvaginal 15 pelvic organ prolapse surgery with mesh?</p> <p>16 A. As they've written it here, may result, I 17 can't really disagree with that. I think, as -- as 18 time has borne out and as we've seen further studies 19 with sacrocolpopexy, we're seeing that this -- the 20 mesh exposure rate is very similar or suture exposure 21 rate. And with abdominally placed mesh you also have 22 the risk of bowel obstruction and adhesions, 23 intraabdominal adhesions.</p> <p>24 Q. I think you've answered my question. I'll</p>	<p>1 which studied whether or not the product was effective 2 for -- strike that.</p> <p>3 Do you agree that native tissue repairs have 4 similar outcomes to synthetic mesh without the risks 5 inherent in mesh use?</p> <p>6 MR. GAGE: Object to form.</p> <p>7 A. (No response.)</p> <p>8 Q. (By Mr. Faes) Why don't I ask a better 9 question? Do you agree that native tissue repairs for 10 the repair of pelvic organ prolapse have similar 11 outcomes to synthetic mesh used for pelvic organ 12 prolapse without the risks inherent in mesh use?</p> <p>13 A. No.</p> <p>14 MR. GAGE: Object to form.</p> <p>15 A. I think the -- in my opinion, the literature 16 is clear that the outcomes are better with mesh 17 augmentation and the risks are similar. The only 18 additional risk is mesh exposure or erosion.</p> <p>19 Q. (By Mr. Faes) Do you agree or disagree that 20 native tissue repair remains the standard of care for 21 the treatment of pelvic organ prolapse in the typical 22 patient?</p> <p>23 A. I disagree. The standard of care is 24 sacrocolpopexy at this point.</p>
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<p>1 object to move to strike after the word "that" just 2 for the record.</p> <p>3 If a synthetic graft product like the Prosimax 4 does not do better than native tissue repair, in terms 5 of safety and efficacy, do you think it should be 6 introduced to the market?</p> <p>7 A. That's a hypothetical question.</p> <p>8 Q. It is.</p> <p>9 A. If any product doesn't show improved safety 10 or efficacy, I don't know why they would want to -- 11 why anyone would want to release it or market it. 12 What would be the point?</p> <p>13 Q. Okay. Do you agree or disagree with the 14 following statement: There is no authoritative -- 15 authoritative paper to support the Prosimax outcomes 16 are superior or even comparable to a colporrhaphy?</p> <p>17 A. I disagree with that statement.</p> <p>18 Q. So if the investigator of a -- on a Prosimax 19 trial were to make that statement to Ethicon, you 20 would disagree with that statement?</p> <p>21 A. Yes. I think we've got some good literature 22 that shows that it is efficacious and safe. And 23 that's also what I saw in my own experience.</p> <p>24 Q. If a primary investigator for a Prosimax trial</p>	<p>1 Q. What exhibit are we on, Doctor? Are we on 9? 2 A. 8. It's 9.</p> <p>3 MR. GAGE: This was one 8.</p> <p>4 A. That's correct.</p> <p>5 MR. GAGE: So 9 would be next. 6 (Exhibit No. 9 marked.)</p> <p>7 Q. (By Mr. Faes) Doctor, I'm going to hand you 8 what's been marked as Exhibit 9 to your deposition.</p> <p>9 MR. FAES: I actually got one of these 10 for you, too, William.</p> <p>11 Q. (By Mr. Faes) Give you a second to review 12 that. And my first question is: Have you seen this 13 document before?</p> <p>14 A. Yes, I have.</p> <p>15 Q. Is this a document that you reviewed and 16 relied upon in forming your opinions in this case?</p> <p>17 A. Yes.</p> <p>18 Q. Do you agree that -- let me read this. This 19 is a document titled FDA strengthens -- strengthens 20 requirement for surgical mesh for the transvaginal 21 repair of pelvic organ prolapse to address safety 22 risks. And it's dated January 4th, 2016.</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p>

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<p>1 Q. It says beginning in the first paragraph, 2 second sentence: The FDA issued one order to 3 reclassify these medical devices from class II, which 4 generally includes moderate-risk devices, to class 5 III, which generally includes high-risk devices. 6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. Do you agree that surgical mesh to repair 9 pelvic organ prolapse are high-risk devices?</p> <p>10 A. No, I don't agree.</p> <p>11 Q. So do you disagree with the FDA's decision to 12 reclassify surgical mesh to a high-risk device?</p> <p>13 A. Yes, I do.</p> <p>14 Q. Do you believe that the Prosimma is a 15 high-risk device?</p> <p>16 A. No, not at all.</p> <p>17 Q. Do you believe that the Prolift is a 18 high-risk device?</p> <p>19 A. No, not at all.</p> <p>20 Q. Do you believe the Gynemesh PS flat mesh is a 21 high-risk device?</p> <p>22 A. No.</p> <p>23 Q. Do you know whether or not the Prolift is now 24 classified as a class III -- strike that.</p>	<p>1 Q. And you don't know obviously, then, if the 2 number of this residual risk score correlates to the 3 device being low risk, moderate risk or high risk?</p> <p>4 A. I don't know.</p> <p>5 Q. And, again, since you've never seen these, 6 you don't know what Ethicon's assessment was for the 7 Prolift, Prosimma or the Gynemesh PS flat mesh with 8 regards to whether it was a low, moderate or high-risk 9 device. Is that correct?</p> <p>10 A. That's correct.</p> <p>11 Q. Now, if you look again at Exhibit No. 9, on 12 the very first paragraph it says: Surgical mesh has 13 been used by surgeons since the 1950s to repair 14 abdominal hernias; in the 1970s, gynecologists began 15 implanting surgical mesh for abdominal repair of 16 pelvic organ prolapse and, in the 1990s, for 17 transvaginal repair of pelvic organ prolapse. In 18 2002, the first flat mesh device with this indication 19 was cleared for use as a class II moderate risk 20 device.</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Do you know whether or not that the first 24 mesh device with this indication that was cleared in</p>
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<p>1 Do you know whether or not the Gynemesh PS 2 flat mesh is now classified as a class III or class II 3 device?</p> <p>4 A. I don't know.</p> <p>5 Q. Do you think that would be important in -- or 6 something you'd like to consider in forming your 7 opinions regarding the Gynemesh PS?</p> <p>8 A. No. I feel very comfortable with it with my 9 experience and with the literature.</p> <p>10 Q. Do you know whether or not Ethicon does 11 internal risk analysis to determine risk scores for 12 those devices -- strike that. I think I phrased that 13 wrong.</p> <p>14 Do you know whether or not Ethicon does 15 internal risk analysis to determine risk scores for 16 the medical devices they sell?</p> <p>17 A. I'm not sure.</p> <p>18 Q. You've never seen a residual risk analysis 19 for the Prosimma, Prolift or Gynemesh PS device?</p> <p>20 A. I don't think I have.</p> <p>21 Q. So you don't recall, sitting here today, 22 whether or not Ethicon assigns a residual risk score 23 when they do these analyses. Is that correct?</p> <p>24 A. That's correct.</p>	<p>1 2002 that it's referring to is the Gynemesh PS?</p> <p>2 A. I don't know.</p> <p>3 Q. So you don't know, sitting here today, 4 whether or not the Gynemesh PS flat mesh was the first 5 mesh device which was cleared with a transvaginal use 6 indication?</p> <p>7 A. I know it -- I think that was the year that 8 it was approved and cleared, but I don't know if it 9 was the first one.</p> <p>10 Q. Good enough. Do you know if Ethicon wanted 11 to sell the Gynemesh PS flat mesh with a transvaginal 12 use indication today, if they would have to submit a 13 premarket approval indication to the FDA because it's 14 now a class III device?</p> <p>15 A. Can you repeat your question, please?</p> <p>16 Q. You know what, I'm going to strike that --</p> <p>17 A. Okay.</p> <p>18 Q. -- and move on. Doctor, on Page 3 of your 19 report -- and feel free to refer back to it if you 20 want. It's already marked as an exhibit. -- you 21 state that the data in women does not support that the 22 Gynemesh Prolene Soft degrades. Is that an opinion 23 you intend to offer in this case?</p> <p>24 A. Absolutely. I feel very strongly about that.</p>

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<p style="text-align: center;">Page 70</p> <p>1 Q. Would you agree that you are not an expert in 2 polymer chemistry?</p> <p>3 A. No, I would not agree with that. I mean, I 4 have dealt with polymers all these years as a surgeon 5 and I was a chemical engineering undergrad and studied 6 polymer science there, so I feel comfortable with 7 polymers and I understand how Gynemesh works in 8 patients in over 2000 patients.</p> <p>9 Q. So you hold yourself out as an expert in 10 polymer chemistry. Is that right?</p> <p>11 A. Yes, as far as it -- as far as it relates to 12 my practice, I certainly do.</p> <p>13 Q. Have you ever done any chemical testing with 14 the Prolene Soft mesh or the mesh in the Prolift or 15 the Prosima to see if it degrades?</p> <p>16 A. No, I haven't done that.</p> <p>17 Q. Have you ever done a microscopic analysis of 18 the Prolene Soft mesh or the mesh that's in the -- 19 which is the mesh that's in the Prolift or in Prosima 20 to determine if it degrades?</p> <p>21 A. No, I haven't.</p> <p>22 Q. Do you -- strike that.</p> <p>23 In support of your opinion regarding mesh 24 degradation you state that the reoperation rates for</p>	<p style="text-align: center;">Page 72</p> <p>1 A. For mesh failure -- what do you mean by "mesh 2 failure"? Do you mean that the prolapse recurred?</p> <p>3 Q. Yes.</p> <p>4 A. In that same compartment or in another 5 compartment?</p> <p>6 Q. Well, let's -- both questions. What 7 do you believe the reoperation rates are for Prolift 8 for prolapse recurring in the same compartment, 9 different compartment, and then both combined?</p> <p>10 A. It's going to be -- for the -- the -- it's 11 going to be around 20 percent per compartment.</p> <p>12 Q. So I'm not sure if that answered my question, 13 so I'll break it down. What do you believe are 14 reoperation rates for Prosima for failures in the same 15 compartment?</p> <p>16 A. For a recurrent -- I don't call it a mesh 17 failure, first of all, because it's not necessarily a 18 fault of the mesh. It's just the way that the pelvis 19 is. There's going to be a certain degree of recurrent 20 prolapse no matter what technique you use.</p> <p>21 Q. Let me see if I can re-ask the question in a 22 way that you can answer with a straight percentage. 23 What do you believe the reoperation rates are for the 24 Prosima for treatment failure in the same compartment?</p>
<p style="text-align: center;">Page 71</p> <p>1 recurrence are low and that cure rates and patient 2 satisfaction is high. Is there anything else you 3 believe supports your opinion?</p> <p>4 A. Well, the literature definitely supports it 5 when we don't see problems that can be related back to 6 degradation in the literature.</p> <p>7 Q. What do you believe the reoperation rates are 8 for the Prosima device?</p> <p>9 A. Oh, five percent, ten percent. And most of 10 those are just small erosions that need to be 11 repaired.</p> <p>12 Q. What do you --</p> <p>13 MR. GAGE: Object to form of the last 14 question. I think you asked a question and the 15 witness give a different answer, so that's all I'm 16 saying.</p> <p>17 Q. (By Mr. Faes) What do you believe the --</p> <p>18 MR. FAES: Yeah, I think she answered 19 about complications, not reoperation, so maybe I asked 20 a bad question.</p> <p>21 Q. (By Mr. Faes) What do you believe the 22 reoperation rates -- strike that.</p> <p>23 What do you believe the reoperation rates are 24 for Prosima for mesh failure?</p>	<p style="text-align: center;">Page 73</p> <p>1 A. Okay. So it's somewhere between ten to 20 2 percent.</p> <p>3 Q. What do you believe the reoperation rates are 4 for the Prosima for treatment failure in a different 5 compartment?</p> <p>6 A. About the same.</p> <p>7 Q. What do you believe the reoperation rates are 8 for the Prosima for treatment failure either in the 9 same compartment or a different compartment?</p> <p>10 A. It would be --</p> <p>11 MR. GAGE: Object the form.</p> <p>12 A. -- about the same, around that --</p> <p>13 Q. (By Mr. Faes) Ten to 20 percent?</p> <p>14 A. Around that range, yeah.</p> <p>15 Q. And I think you already anticipated my 16 question and answered it, but what do you believe the 17 reoperation rates are for Prosima for mesh extrusion 18 or -- strike that. I'm going to ask it a little bit 19 different question.</p> <p>20 What do you believe the reoperation rates are 21 for the Prosima to treat complications, all 22 complications, excluding treatment failure?</p> <p>23 A. Excluding treatment failure, somewhere 24 between five and ten percent.</p>

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<p>1 Q. What do you believe the reoperation rates are 2 for the Prosima to treat complications or treatment 3 failure in any compartment?</p> <p>4 A. So somewhere between five and 20 percent. 5 That's looking at the literature, looking at my own 6 experience.</p> <p>7 Q. So you -- as you sit here today, you don't 8 believe that a reoperation rate for treatment failure 9 of ten to 20 percent and a reoperation rate for 10 complications of five to ten percent is evidence that 11 the Gynemesh PS mesh in the Prosima degrades?</p> <p>12 A. No, not at all. There's no correlation 13 there.</p> <p>14 Q. Is there a number it would reach -- it could 15 reach in order for you to change or reconsider your 16 opinion that the data in women doesn't support that 17 the Gynemesh PS degrades?</p> <p>18 A. I can't -- I can't even conceive of that, 19 because it does not even -- it does not degrade in any 20 way, so it's just a hypothetical question. So, yes, 21 there's no --</p> <p>22 Q. So if there --</p> <p>23 A. There's nothing you could tell me that would 24 make me say, oh, that's because of degradation,</p>	<p>1 support of your opinion that the data in women does 2 not support that the Gynemesh PS degrades, you state 3 that the reoperation rates for recurrence are low, 4 that the cure rates and patient satisfaction are high. 5 Is there anything else that you're relying on to 6 support your opinion that the data in women does not 7 support that the Gynemesh PS degrades?</p> <p>8 A. Well, also, apart from these, sort of, side 9 studies where they show, quote, unquote, degradation, 10 which I think is just probably the biofilm, in other 11 studies, where they -- where they remove the mesh, the 12 mesh is there. You know, it's not -- it doesn't 13 disappear. It doesn't degrade over time. I mean, if 14 Prolene degraded, they would not use it in cardiac 15 surgery to rely on sewing together arteries. So this 16 whole theory of degradation is just -- just bogus in 17 my opinion.</p> <p>18 Q. So if I understand you correctly, you're 19 relying on literature to support your opinion that the 20 Gynemesh PS doesn't degrade?</p> <p>21 A. And my own clinical experience, my own 22 clinical experience with my patient success and 23 satisfaction with it. And in the cases where I've 24 removed mesh, you know, grossly examining the mesh --</p>
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<p>1 because it doesn't happen.</p> <p>2 Q. But if I understand you correctly, you're 3 using the -- you rely on the fact that reoperation 4 rates for recurrence are low and cure rates and 5 patient satisfaction is high is the basis for 6 your opinion that the mesh doesn't degrade. 7 Right?</p> <p>8 A. Right.</p> <p>9 Q. So you're saying -- telling me that there's 10 no number that that -- that those reoperation rates 11 could rise to that would cause you to reconsider your 12 opinion?</p> <p>13 A. No. I mean, that's part of the basis. 14 That's not the whole basis. That's just -- first of 15 all, we're starting with the fact that it doesn't 16 degrade and then this is the supportive reason to show 17 that it doesn't. But the converse is not necessarily 18 true. If this happens, that doesn't mean that it 19 degrades, if that makes sense.</p> <p>20 Q. So, again, I think I asked you this 21 question earlier -- maybe I didn't or maybe I've 22 already forgotten the experts that your -- strike 23 that. I'm just babbling now.</p> <p>24 So let me just ask you a new question: In</p>	<p>1 yeah, I didn't do a microscopic electron microscopy on 2 the mesh, but, you know, it's not like you see it 3 disintegrating. It's not falling apart in front of 4 your eyes.</p> <p>5 Q. Have -- or do you believe that the mesh has 6 to be disintegrating for falling apart in front of 7 your eyes in order to have a clinical impact on the 8 patient? Do you believe -- strike that. Let me ask a 9 different question.</p> <p>10 Do you believe that -- actually, let me start 11 over.</p> <p>12 Do you believe that polypropylene doesn't 13 degrade at all or do you just believe that the 14 polypropylene mesh in the pelvic organ prolapse 15 products that you're offering opinion on -- opinions 16 on don't grade?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 A. I don't think it degrades at all. If it does 19 degrade, microscopically, there's absolutely no 20 clinical effect on patients --</p> <p>21 Q. (By Mr. Faes) So your --</p> <p>22 A. -- and there's no implication to it.</p> <p>23 Q. Your opinion is that no polypropylene 24 anywhere degrades?</p>

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<p>1 A. Like I said, if it does degrade, 2 microscopically, there's no clinical impact, so it's a 3 nonissue.</p> <p>4 Q. I'm not sure if I got an answer to my 5 question, though. Is it your opinion that no 6 polypropylene anywhere degrades or do you agree that 7 some polypropylene can degrade under the right 8 circumstances?</p> <p>9 A. I think it potentially could degrade under 10 the right circumstances. Anything can degrade under 11 the right circumstances. But does it clinically have 12 any impact, no.</p> <p>13 Q. Do you believe that when polypropylene mesh 14 degrades, it can become -- strike that.</p> <p>15 Do you believe that when polypropylene 16 degrades one of the things that can occur is that the 17 polypropylene can become brittle?</p> <p>18 MR. GAGE: Object to form.</p> <p>19 A. No.</p> <p>20 Q. (By Mr. Faes) Do you know what fishing line 21 is made out of?</p> <p>22 A. No, I don't.</p> <p>23 Q. You don't know that fishing line is made out 24 of polypropylene?</p>	<p>1 A. Not to the same degree.</p> <p>2 Q. (By Mr. Faes) Do you know whether peroxides 3 have an effect on polypropylene degradation?</p> <p>4 A. I believe that they can, yes.</p> <p>5 Q. So, just so I understand your answer, you do 6 believe that peroxides can accelerate or cause 7 polypropylene to degrade?</p> <p>8 A. In the right concentration, yes.</p> <p>9 Q. What do you believe the patient satisfaction 10 rates are for the Prosima device?</p> <p>11 A. They're very high. They're 80 to 90 percent.</p> <p>12 Q. And where are you getting that information 13 from?</p> <p>14 A. From multiple studies.</p> <p>15 Q. What do you believe the reoperation rates are 16 for the Prolift device for complications?</p> <p>17 A. It's around the same as the Prosima, five to 18 20 percent.</p> <p>19 Q. That's a pretty big range, isn't it, Doctor?</p> <p>20 A. Yeah, and the studies are -- that's pretty 21 much the range that you're going to find in the 22 studies.</p> <p>23 Q. Would you agree that the erosion or extrusion 24 rate for the Prolift can range from 15 to 20 percent?</p>
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<p>1 A. No, I didn't know that.</p> <p>2 Q. Have you ever gone fishing?</p> <p>3 A. Yes.</p> <p>4 Q. Have you ever had to replace your fishing 5 line because the line got brittle from the previous 6 year?</p> <p>7 A. Yes. But that's a completely different 8 circumstance than something that's implanted in the 9 body.</p> <p>10 Q. Well, I wasn't asking about things that were 11 implanted in the body. I'm asking -- so you'd agree 12 with that example, that polypropylene under the right 13 circumstances can degrade?</p> <p>14 A. Yeah, sure.</p> <p>15 Q. You also talked about the fact that 16 polypropylene sutures are used -- or Prolene sutures, 17 rather, are used in cardiac surgery. Do you believe 18 that the environment in the vagina is the same as the 19 environment in the cardiac cavity?</p> <p>20 A. No. It's different.</p> <p>21 Q. In fact, you know that there are peroxides 22 present in the vagina and there are not peroxides 23 present in the cardiac cavity. Right?</p> <p>24 MR. GAGE: Object to form.</p>	<p>1 A. Some studies show that, but most studies it's 2 closer to the five to ten percent range. Eight 3 percent seems to be the number that comes up a lot.</p> <p>4 Q. So you did -- if someone were to tell you 5 that the overall erosion or exposure or extrusion 6 rates for the Prolift was in the 15 to 20 percent 7 range, you'd disagree with that?</p> <p>8 A. Yeah. That's -- that's high. I know some 9 studies have shown that and have shown even higher in 10 small studies, but -- but looking at the large 11 database studies, the rates are not that high.</p> <p>12 Q. Do you know Dr. Joe Carbone?</p> <p>13 A. Yes.</p> <p>14 Q. You've met Dr. Joe Carbone --</p> <p>15 A. I have.</p> <p>16 Q. -- before. Right? In fact, you both 17 attended the 2011 Ethicon Pelvic Floor Summit in 18 Sonoma together?</p> <p>19 A. Yes.</p> <p>20 Q. Where there was wine tasting and dinner?</p> <p>21 A. Yes.</p> <p>22 Q. So if Dr. Carbone told me last week that he 23 believes the overall erosion or extrusion rates for 24 the Prolift device is 15 to 20 percent, would you</p>

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<p>1 disagree with him?</p> <p>2 A. With all due respect to Dr. Carbone, I think 3 -- I don't think the literature bears out that -- that 4 high a rate. And my personal experience certainly is 5 not that high. And I think, talking to my colleagues, 6 it's not that high.</p> <p>7 Q. But you do agree that, at least in some 8 studies, the erosion or exposure rate can be as high 9 as 20 percent with the Prolift. Right?</p> <p>10 A. I have seen studies that show that yes.</p> <p>11 Q. And you're familiar with the Iglesia study?</p> <p>12 A. Yes.</p> <p>13 Q. And you know that the exposure and erosion 14 rate for the Prolift in that study was greater than 15 15 percent?</p> <p>16 A. Yes, as well as the suture exposure rate was 17 also 15 percent in the native tissue repairs.</p> <p>18 MR. FAES: I'm going to object and move 19 to strike after the answer "yes." I didn't ask 20 anything about suture exposure rates.</p> <p>21 Q. (By Mr. Faes) And you know that that study 22 was stopped by Dr. Iglesia and her colleagues because 23 of their concern about the erosion and exposure rates. 24 Correct?</p>	<p>1 literature with my own experience and that's where I 2 form my opinions, so I would have to disagree with 3 them on that.</p> <p>4 Q. (By Mr. Faes) Yeah. I'm going to have to 5 re-ask it, because there's a lot of nonresponsive 6 information in there. I'm going to ask a 7 hypothetical: Assuming that the FDA said that they 8 did not consider Dr. Iglesia an outlier, if they did 9 indeed say that, that's another instance in which you 10 would disagree with the FDA. Is that correct?</p> <p>11 A. That's correct.</p> <p>12 MR. GAGE: Object to form.</p> <p>13 Q. (By Mr. Faes) What do you believe are the 14 patient satisfaction rates with the Prolift device?</p> <p>15 A. Again, very high, 75 to 90 percent.</p> <p>16 Q. At what time frame? Are you calculating 17 patient satisfaction rates at one year, three years?</p> <p>18 A. Well, the -- you know -- studies go -- most 19 -- a lot -- most of the studies are one to two years, 20 but there are some studies that go out further to 21 seven years.</p> <p>22 Q. What's the longest study that you're aware 23 of, the longest follow-up study you're aware of that 24 utilized the Gynemesh PS mesh, whether it be in the</p>
<p style="text-align: center;">Page 83</p> <p>1 A. That's correct.</p> <p>2 Q. Do you consider Dr. Iglesia an outlier?</p> <p>3 A. Yes, I do.</p> <p>4 Q. Do you know whether the FDA considers Dr. 5 Iglesia an outlier?</p> <p>6 A. I don't know what they think about 7 Dr. Iglesia.</p> <p>8 Q. So you've never seen records from meetings 9 that Ethicon had with the FDA regarding the 522 orders 10 where the FDA told Ethicon that they did not consider 11 Dr. Iglesia an outlier. Is that fair?</p> <p>12 MR. GAGE: Object to form.</p> <p>13 A. You know, I've seen so many documents. As I 14 sit here today, I'm not sure if I saw that or not. I 15 probably did.</p> <p>16 Q. (By Mr. Faes) So I'm going to ask a 17 hypothetical: Assuming that the FDA said that they 18 did not consider Dr. Iglesia an outlier, that's 19 another instance in which you would agree with -- 20 disagree with the FDA. Correct?</p> <p>21 MR. GAGE: Object the form.</p> <p>22 A. With all due respect to the FDA and 23 Dr. Iglesia, I look at the full body of literature. I 24 don't look at one study. I compare the full body of</p>	<p style="text-align: center;">Page 85</p> <p>1 Prolift or the Prosima or as a flat mesh?</p> <p>2 A. I believe it's seven years.</p> <p>3 Q. Do you recall what study or studies go out to 4 seven years?</p> <p>5 A. I would have to take a minute to refresh my 6 memory.</p> <p>7 Q. Do you recall, without refreshing your 8 memory, whether it's more than one or if it's. . .</p> <p>9 A. I believe there were two studies.</p> <p>10 Q. Do you believe that if polypropylene mesh 11 were to break down or degrade, it could lead to an 12 erosion or an exposure?</p> <p>13 A. We're talking hypothetically. And I would 14 think that if it were degrading, then it would be just 15 disappearing. And so I'm not sure how that could 16 cause an erosion or an exposure.</p> <p>17 Q. Do you believe that mesh degrading or 18 breaking down could lead to an unintended tissue 19 reaction?</p> <p>20 A. Again, hypothetically, because as I stated 21 before, I don't think it does degrade, but if there's 22 some product that did degrade, then, yes, that could 23 cause an inflammatory reaction.</p> <p>24 Q. Can an inflammatory reaction or unintended</p>

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<p style="text-align: center;">Page 86</p> <p>1 tissue reaction cause the body to push the mesh out of 2 the body causing it to be eroded or exposed? 3 A. Hypothetically, if there's an inflammatory 4 reaction, you could have a tissue breakdown and have a 5 mesh exposure. I wouldn't say it's pushing it out of 6 the body, but there could -- if there's a tissue 7 breakdown, you could have an exposure of the mesh. 8 Q. If polypropylene were to become brittle, as 9 we discussed with the fishing line example, could that 10 lead to an erosion? 11 A. I think it would depend on how it how it -- 12 how it were oriented. And, again, I'm not conceding 13 that it degrades or becomes brittle in the body. But 14 hypothetically, if it were poking out towards the 15 tissue, something could break down, I suppose. 16 Q. You'd agree that sharp edges of the mesh 17 could cause an erosion? 18 A. If the mesh is not oriented properly and not 19 placed properly, that could cause an erosion from a 20 sharp edge. It's not because of the mesh. It's the 21 way that it's put in. 22 Q. If the mesh becomes -- hypothetically, again, 23 if the mesh becomes brittle, could that lead to 24 patient discomfort?</p>	<p style="text-align: center;">Page 88</p> <p>1 Gynemesh, Prolift and Prosima. 2 Q. So, approximately, how many studies did you 3 determine had been done on the Vypro mesh in pelvic 4 reconstructive surgery? 5 A. I don't -- I don't have a number, but it's 6 not many at all. 7 Q. How many studies did you find where PD 8 -- PVDF mesh had been studied in pelvic reconstructive 9 surgery? 10 A. I don't have a number. 11 Q. How many Ultrapro studies did you find that 12 had been studied in pelvic reconstructive surgery? 13 A. I don't have a number for that. 14 Q. How many Elevate studies did you find that 15 had been studied in pelvic reconstructive surgery? 16 A. I'm sorry. I don't have an exact number. 17 Q. So you can't quote a number as you're sitting 18 here today, but you believe it's less? 19 A. Yes. 20 Q. Do you know if it's 50 percent less, 25 21 percent less? 22 A. It's a lot less. 23 Q. How did you determine it was less? What 24 methodology did you use?</p>
<p style="text-align: center;">Page 87</p> <p>1 A. I'm not sure. 2 Q. On Page 3 of your report you state that 3 Gynemesh PS has been the most studied mesh in pelvic 4 reconstructive surgery. Is that an opinion you intend 5 to offer in this case? 6 A. Yes. 7 Q. When you say that it's the most studied mesh 8 in pelvic reconstructive surgery, what do you mean by 9 that? Do you mean that it's had the most number of 10 studies performed or that the -- had the most number 11 of patients studied in those studies or both, if that 12 makes sense? It's kind of an ineloquent question. 13 MR. GAGE: Object to form. 14 A. Both, the most studies, the most number of 15 patients, the most randomized controlled studies. 16 Q. (By Mr. Faes) So what other meshes did you 17 compare it to to make that determination that it was 18 the most studied -- 19 A. Well -- 20 Q. -- in pelvic reconstructive surgery? 21 A. The Vypro, the PVDF, Ultrapro. And then 22 there's other kits, as well, that are also 23 polypropylene mesh, like the Elevate, that have been 24 studied quite a bit, as well, but not as much as the</p>	<p style="text-align: center;">Page 89</p> <p>1 A. Well, you can just do a PubMed search. 2 Q. Did you keep any documentation of your PubMed 3 searches in terms of how many studies for these other 4 four meshes? 5 A. No, I did not. 6 Q. Did you compare the Prolene -- actually, I'm 7 going to strike that. 8 Different question: Did you do any kind of 9 systematic review of the literature on those four 10 meshes to determine whether the quality of those 11 studies was better or worse than the quality of the 12 studies on the Gynemesh PS mesh? 13 A. I just did sort of a survey of the studies. 14 I didn't go in depth. 15 Q. So you'd agree that it wasn't any kind of a 16 systematic review? 17 A. No. 18 Q. Did you compare -- in regards to this 19 opinion, that it's the most studied mesh in pelvic 20 reconstructive surgery, did you do any comparison to 21 the traditional Prolene mesh, see how many studies 22 there were where that had been used? 23 A. No, I didn't. 24 Q. Same question: The IntePro Lite mesh?</p>

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1 A. No.	1 Q. Is that something you intend to do prior to trial?
2 Q. What about the Marlex mesh, which is now called the Bard mesh?	3 A. Perhaps.
4 A. Uh-huh.	4 MR. FAES: I would ask counsel, if such a demonstrative is ever created, that that be produced to us.
5 MR. GAGE: You need to say "yes," not --	7 Q. (By Mr. Faes) Do you know how many out of those hundred are randomized controlled trials?
6 THE WITNESS: No. Yeah. I'm just acknowledging that I understood the question. Sorry.	9 A. I don't have a number off the top of my head. Numerous.
7	11 Q. Do you know how many of those studies are Gynemesh PS flat mesh by itself?
8 A. No, I didn't.	13 A. I don't have a number.
9 Q. (By Mr. Faes) Would you agree that native tissue repair of pelvic organ prolapse is more studied than the Gynemesh PS has been in pelvic reconstructive surgery?	14 Q. Do you know if there have been any randomized controlled trials of Gynemesh PS flat mesh comparing it to comparator device or procedure?
10 A. I am not sure about that. My gut feeling is that the Gynemesh is more studied, but I'd have to --	16 A. I can't recall right now.
11 I'd have to -- I'd have to look at that.	18 Q. Do you know if there are any randomized controlled trials comparing the Prosima device to an alternative device or procedure?
12	21 A. Yes, absolutely.
13 Q. So -- but it's fair to say, as you sit here today --	22 Q. How many of those -- how many randomized controlled trials do you believe there are that compare the Prosima device to a different device
14 A. Uh-huh.	
15 Q. -- you've never looked at that and you don't know, one way or the other, whether native tissue repair for repair of pelvic organ prolapse is more studied than the Gynemesh PS has been in pelvic reconstructive surgery?	
16 A. I don't know.	
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1 Q. You haven't looked at that question?	1 or procedure?
2 A. I haven't looked at that.	2 A. I believe there's about five or six.
3 Q. Okay. You also state in your report that there are numerous randomized controlled trials and over a hundred studies which demonstrate that the Gynemesh PS when used by itself or in the Prolift and Prosima devices -- I think I said that wrong. Strike that and I'll ask a new question.	3 Q. In the hundred studies that you say demonstrate the use of Gynemesh PS, when used by itself or in the Prolift or Prosima devices, do you know how many of those studies use Gynemesh PS abdominally rather than transvaginally?
4	8 A. I don't recall. Not very many.
5	9 Q. In your report you state that there -- you don't believe that there is any evidence that the Prolene mesh is cytotoxic. Is that correct?
6	10 A. That's correct.
7	11 Q. Is that an opinion you intend to offer in this case?
8	12 A. Yes.
9 You say in your report that there are numerous randomized controlled trials and over a hundred studies which demonstrate that the Gynemesh PS when used by itself or in the Prolift or Prosima devices. Is that correct?	13 Q. Have you studied what happens to tissue when it is exposed to a cytotoxic substance?
10	14 A. I'm sure in biology or in medical school we studied, you know, cytotoxicity and what happens to tissue in that circumstance.
11	15 Q. As you sit here today, can you tell me what the clinical effect would be to tissue if it were opposed [sic] to a cytotoxic substance?
12	16 A. Necrosis. Inflammation, necrosis.
13	
14 A. That's correct.	
15 Q. Do you know what the exact number is?	
16 A. No, I don't.	
17 Q. Do you have any documentation that you have or a list that you intend to refer to at trial as to what those greater than a hundred studies are?	
18	
19	
20 A. None other than my reliance materials.	
21 Q. But you've never separately broken them out, those hundred out of your reliance list for use as a demonstrative at trial or anything like that?	
22	
23	
24 A. No.	

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<p>1 Q. Would you agree that necrotized or -- strike 2 that.</p> <p>3 Would you agree that necrotized tissue 4 surrounding a mesh could lead to erosion or exposure 5 of the mesh?</p> <p>6 A. Yes.</p> <p>7 Q. So isn't one clinical manifestation -- 8 potential clinical manifestation of -- strike that.</p> <p>9 So if you agree that one potential effect of 10 being exposed to a cytotoxic substance is that the 11 tissue can undergo necrosis and you agree that 12 necrotized tissue surrounding the mesh can lead to an 13 erosion or exposure of the mesh, isn't a study that 14 shows an erosion or exposure rate of 15 to 20 percent 15 evidence that the mesh is, indeed, cytotoxic?</p> <p>16 MR. GAGE: Object to form.</p> <p>17 A. No, not at all. The necrosis around the 18 wound can be due to tissue handling, the state of the 19 tissue, cautery of the edges, improper sewing 20 technique, history of smoking, diabetes, poor blood 21 flow. There's just innumerable reasons for necrosis. 22 And most of the erosions are right in the suture line, 23 so that's a wound healing issue. If it -- if mesh 24 were cytotoxic, you would see erosions all over the</p>	<p>1 Q. -- if you want to keep going, I won't cut you 2 off. So you've listed multiple potential causes 3 of tissue necrosis. We can agree that there are 4 multiple potential causes of tissue necrosis. 5 Correct?</p> <p>6 A. Yes.</p> <p>7 Q. And we can also agree that one potential 8 cause of tissue necrosis is the tissue being exposed 9 to a cytotoxic substance. Is that correct?</p> <p>10 A. That's correct.</p> <p>11 Q. On Page 4 of your report you state that 12 plaintiffs' experts have said that there are safer or 13 better meshes, that these meshes have not been 14 demonstrated to be more efficacious based on reliable 15 scientific literature like the Gyne -- the Gynemesh 16 PS. Is that correct?</p> <p>17 A. That's correct.</p> <p>18 Q. Is that an opinion you tend to offer in this 19 case?</p> <p>20 A. Yes.</p> <p>21 Q. Now, specifically, in your report, you 22 mention DynaMesh, Vypro and Ultrapro. Is that right?</p> <p>23 A. Correct.</p> <p>24 Q. Are there any other meshes that you have</p>
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<p>1 place and you don't see that. You see them -- the 2 vast majority are right in the suture line.</p> <p>3 Q. You don't think a study that shows an erosion 4 rate of 15 to 20 percent is an erosion all over the 5 place?</p> <p>6 A. No. No. I'm talking about -- I'm talking 7 about erosion on the side of the vagina, you know, not 8 just in the suture line. If it's in the suture line, 9 that's a wound healing problem. If it -- if the mesh 10 were cytotoxic, you would see holes on this side of 11 the vagina and over here, not just in the incision 12 line.</p> <p>13 Q. So is it your testimony that you've never 14 seen an erosion any place other than in the incision 15 line?</p> <p>16 A. No, I'm not saying that. I'm not saying that 17 at all. I have seen that on the sides. Usually an 18 arm that was not placed properly through the sulcus, 19 but --</p> <p>20 Q. I think you've you've answered my question.</p> <p>21 A. Okay.</p> <p>22 Q. I'm going to move to strike everything after 23 that anyway, but --</p> <p>24 A. Okay.</p>	<p>1 studied that you believe have not been demonstrated to 2 be more efficacious based on reliable scientific 3 literature like the Gynemesh PS?</p> <p>4 A. No.</p> <p>5 MR. GAGE: Just take a quick bathroom 6 break.</p> <p>7 MR. FAES: Same here. Let's do it real 8 quick.</p> <p>9 THE WITNESS: Yeah.</p> <p>10 (Break.)</p> <p>11 Q. (By Mr. Faes) Dr. Pramudji, we're back on 12 the record after a short break. Are you ready to 13 proceed?</p> <p>14 A. Yes.</p> <p>15 Q. Before the break we were talking about meshes 16 that you believe have not been demonstrated to be 17 safer and more efficacious based on the reliable 18 scientific literature like Gynemesh PS. Did you study 19 the Restorelle mesh?</p> <p>20 A. No, I did not.</p> <p>21 Q. And that's currently your mesh of choice for 22 ASC. Correct?</p> <p>23 A. Yes, that's correct.</p> <p>24 Q. Did you study the IntePro mesh?</p>

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<p>1 A. No, I did not.</p> <p>2 Q. Did you study the IntePro Lite mesh?</p> <p>3 A. No.</p> <p>4 Q. Did you study the Elevate mesh?</p> <p>5 A. No.</p> <p>6 Q. What about the Uphold mesh?</p> <p>7 A. No.</p> <p>8 Q. No. Did you know that Ethicon was developing 9 a Prosima Plus M device which would have used the 10 Ultrapro mesh, rather than the Gynemesh PS mesh just 11 like the Prolift Plus M?</p> <p>12 A. Yes, I was aware of that.</p> <p>13 Q. When were you made aware of that?</p> <p>14 A. Pretty early on, because we were -- we were 15 asking for it, because we liked the Prolift Plus M 16 mesh and we were wondering why the new product was 17 made with the Gynemesh PS versus the Prolift Plus M 18 mesh.</p> <p>19 Q. Do you anticipate that if the Prosima Plus M 20 had been made available with the Ultrapro mesh, do you 21 believe that would have become your device of choice 22 over the traditional Prosima, just like the Prolift 23 Plus M became your device of choice over the Prolift?</p> <p>24 MR. GAGE: Object to form.</p>	<p>1 MR. GAGE: Object to form.</p> <p>2 A. I'm sorry to interrupt. Yes, that's correct.</p> <p>3 Q. (By Mr. Faes) Do you know what the weight in 4 grams per meter squared of the Gynemesh PS mesh is?</p> <p>5 A. I can't remember at this moment. I used to 6 know. I'd have the look it up.</p> <p>7 Q. On Page 5 you state -- of your report you 8 state that the Prosima is minimally invasive compared 9 to the abdominal -- abdominal sacrocolpopexy and less 10 morbid. Is that an opinion you intend to offer in 11 this case?</p> <p>12 A. Yes.</p> <p>13 Q. First of all, let me ask you this: What do 14 you mean by less morbid?</p> <p>15 A. Less effect on the body. With the 16 sacrocolpopexy, you have more dissection, you have 17 more risk of bowel complications compared to Prosima.</p> <p>18 Q. Is there anything else about the ASC 19 procedure that you believe is more morbid than the 20 Prosima procedure?</p> <p>21 A. It also has a risk of hernia, injury to major 22 vessels, bowel obstruction, adhesions.</p> <p>23 Q. Do you believe that the Prosima device 24 doesn't carry with it a risk of hernia?</p>
<p style="text-align: center;">Page 99</p> <p>1 A. I'm not sure. I would have to try it out and 2 see if I got similar results with it.</p> <p>3 Q. (By Mr. Faes) Do you know why the Prosima 4 Plus M device ultimately never came to market?</p> <p>5 A. I don't know why.</p> <p>6 Q. Can you -- well, this is going to be an easy 7 question because there's hardly any kits left on 8 the market, but can you point to a kit for the 9 repair of pelvic organ prolapse which is on the market 10 today which uses a mesh that is heavier in weight than 11 the Gynemesh PS mesh?</p> <p>12 MR. GAGE: Object to form.</p> <p>13 A. No, I can't.</p> <p>14 Q. (By Mr. Faes) In fact, as you sit here 15 today, do you know that all of the mesh kits still on 16 the market have mesh that are lighter in weight than 17 the Gynemesh PS mesh?</p> <p>18 MR. GAGE: Object to form.</p> <p>19 A. I think they're very similar, maybe slightly 20 lighter.</p> <p>21 Q. (By Mr. Faes) But, certainly, none are 22 heavier than the --</p> <p>23 A. That's correct.</p> <p>24 Q. -- Gynemesh PS mesh?</p>	<p style="text-align: center;">Page 101</p> <p>1 A. I'm talking about abdominal wall hernia, to 2 be clear.</p> <p>3 Q. Okay.</p> <p>4 A. So because of the trocars or the incision for 5 an abdominal sacrocolpopexy, there's going to be a 6 risk of abdominal wall hernia.</p> <p>7 Q. And is that a risk that -- is that not a risk 8 of the Prosima device in your opinion?</p> <p>9 A. Right, because there's no abdominal wall 10 incision for a Prosima.</p> <p>11 Q. Can -- is -- can the Prosima device cause 12 other hernias, such as an inguinal hernia.</p> <p>13 A. No, it cannot cause that.</p> <p>14 Q. Do you believe the Prosima device doesn't 15 have a risk of bowel injury?</p> <p>16 A. It's a very small risk. If you have apical 17 dissection into an enterocele, it could happen. Or if 18 you're doing a posterior Prosima, you have a risk of 19 rectal injury, but it's a very small risk.</p> <p>20 Q. Do you believe it's a --</p> <p>21 A. And it's --</p> <p>22 Q. -- smaller risk than the risk of bowel injury 23 with the ASC?</p> <p>24 A. Yes, much smaller risk.</p>

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<p>1 Q. Now, you state that the Prosima device is 2 less invasive. Would you agree that a doctor or 3 patient might choose a more invasive surgery to avoid 4 potentially life complications of a less invasive 5 device or procedure?</p> <p>6 A. What are "life complications"?</p> <p>7 Q. Did I say life com -- I meant life-changing 8 complications.</p> <p>9 A. Oh, okay.</p> <p>10 Q. So let me -- did -- is that not what I said?</p> <p>11 MR. GAGE: Yeah, I'm going to -- if 12 you're going to rephrase -- if you'll withdraw and 13 rephrase the question.</p> <p>14 MR. FAES: Yeah, I'll withdraw it and 15 rephrase it.</p> <p>16 MR. GAGE: Thank you.</p> <p>17 Q. (By Mr. Faes) Would you agree that a doctor 18 or patient might choose a more invasive surgery to 19 avoid potentially life-changing complications of a 20 less invasive device or procedure?</p> <p>21 A. Yes, I agree with that statement.</p> <p>22 Q. Would you agree that a doctor and patient 23 should know about all of the potentially life-changing 24 complications of the device or the procedure, so they</p>	<p>1 placed?</p> <p>2 A. I can agree with that, although I would say 3 that I've never seen that or heard of it, but 4 hypothetically, that -- I would agree with that 5 statement.</p> <p>6 Q. You've never seen or heard of a vaginal 7 support device that needed to be removed prior to the 8 21 days elapsing because of an apparent infection?</p> <p>9 A. No.</p> <p>10 Q. That's not cited on Page 41 of your report in 11 an article?</p> <p>12 A. Oh, I was talking about my own experience. 13 Sorry.</p> <p>14 Q. Oh, okay.</p> <p>15 A. Yeah.</p> <p>16 Q. Okay. So you're aware that that --</p> <p>17 A. Yes.</p> <p>18 Q. -- that can occur?</p> <p>19 A. Yes.</p> <p>20 Q. Now, you've testified before that you're 21 familiar with the ProteGen project -- ProteGen 22 product. Correct?</p> <p>23 A. Correct.</p> <p>24 Q. And you testified that you know that the</p>
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<p>1 can make an informed choice about what device or 2 procedure they would like to have performed on them?</p> <p>3 A. I think a doctor and their patient need to 4 know about potential complications that can occur with 5 any surgery that they're going to have, knowing 6 realistically that you may not be able to anticipate 7 rare complications.</p> <p>8 Q. But even if a complication is rare, you would 9 -- if it's potentially life-changing or devastating, 10 you would agree that it's important for both the 11 doctor and patient to know about that, in order to 12 make an informed choice about whether they want to 13 proceed with that surgery?</p> <p>14 A. Yes, that's fair.</p> <p>15 Q. Would you agree that if a -- even if a 16 Prosima device is placed correctly by a surgeon, the 17 vaginal support device can fall out on its own before 18 the 21-day prescribed healing period has lapsed?</p> <p>19 A. That can happen, yes, depending on how their 20 body handles the micral suture.</p> <p>21 Q. Would you agree that if an infection occurs 22 around the vaginal support device, removal of that 23 vaginal support device is indicated and necessary even 24 if the prescribed 21 days had not passed since it was</p>	<p>1 ProteGen was removed from the market because the 2 erosion rates were unacceptably high?</p> <p>3 A. That's correct.</p> <p>4 Q. Do you know what the reported rates of 5 erosion were for the ProteGen?</p> <p>6 A. I can't recall right now.</p> <p>7 Q. How high would the erosion and exposure rates 8 for the Prosima need to be in order for you to say the 9 erosion rate was unacceptably high?</p> <p>10 A. I think I would feel uncomfortable if I were 11 seeing an erosion rate upwards of 30 percent.</p> <p>12 Q. So if the erosion rate for the Prosima were 13 25 percent, you wouldn't say that that was 14 unacceptably high?</p> <p>15 A. No.</p> <p>16 Q. One in four patients had an erosion or 17 exposure?</p> <p>18 A. I would -- I would think twice about it and 19 it would depend on how bad the erosions were and what 20 kind of treatment they needed and who -- who they are, 21 because as you know from the literature a lot of 22 patients can live their -- with an erosion, a small 23 erosion. So there's a few factors to take into 24 consideration. That's kind of a gray area. You have</p>

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<p>1 to take everything into consideration.</p> <p>2 Q. But anything 30 percent or higher --</p> <p>3 A. Yeah.</p> <p>4 Q. -- with the Prosima you would find</p> <p>5 unacceptably high?</p> <p>6 A. I think, if I had one in three, that would --</p> <p>7 that would be a little bit high.</p> <p>8 Q. Is your answer the same for the Prolift</p> <p>9 device?</p> <p>10 A. Yes.</p> <p>11 Q. Is it the same for the Gynemesh PS flat mesh?</p> <p>12 A. Yes.</p> <p>13 Q. Do you intend to offer an opinion in this</p> <p>14 case as to whether the warnings in the Prosima IFU</p> <p>15 were sufficient to apprise doctors of the risks of</p> <p>16 this product?</p> <p>17 A. Yes, I believe they were sufficient.</p> <p>18 Q. Do you know what the standards were that</p> <p>19 Ethicon applied in terms of what needed to be included</p> <p>20 in the warnings about the Prosima?</p> <p>21 A. Yes.</p> <p>22 Q. And what standards do you believe Ethicon</p> <p>23 applied regarding what needed to be included in the</p> <p>24 warnings about Prosima?</p>	<p>1 just read it for the first time?</p> <p>2 A. That's correct.</p> <p>3 Q. If something in the IFU changes, is there any</p> <p>4 way that you would know if the information in the IFU</p> <p>5 had changed?</p> <p>6 A. Not unless someone told me about it.</p> <p>7 Q. In all your years implanting products for --</p> <p>8 strike that.</p> <p>9 In all of your years of implanting products</p> <p>10 manufactured by Ethicon, has any Ethicon</p> <p>11 representative or sales rep or anybody whoever -- who</p> <p>12 works for Ethicon ever came to you and told you that</p> <p>13 the IFU for a product had been updated?</p> <p>14 A. Not that I can recall.</p> <p>15 Q. Do you know if the Prosima IFU was ever</p> <p>16 updated?</p> <p>17 A. I'm not sure about that one.</p> <p>18 Q. Do you know if the Gynemesh PS IFU was ever</p> <p>19 updated?</p> <p>20 A. I can't recall.</p> <p>21 Q. Do you know if the Gynemesh PS IFU was</p> <p>22 updated this year?</p> <p>23 A. Not that I can recall right now.</p> <p>24 Q. When you read an IFU, do you assume that the</p>
<p style="text-align: center;">Page 107</p> <p>1 A. I think they were -- you know -- excuse me --</p> <p>2 complications that had a certain degree of frequency</p> <p>3 and severity and anything that could potentially be</p> <p>4 life changing that they would try to include.</p> <p>5 Q. I apologize if you've been asked these next</p> <p>6 couple questions before, but you've been deposed,</p> <p>7 what, five times and I can't remember everything you</p> <p>8 said.</p> <p>9 MR. GAGE: Perfect. Perfect.</p> <p>10 Q. (By Mr. Faes) Have you ever in your career</p> <p>11 been involved in writing or preparing writings for a</p> <p>12 medical device?</p> <p>13 A. No.</p> <p>14 Q. That's wrong in my outline. Have you ever</p> <p>15 been in your career involved in writing or preparing</p> <p>16 IFUs for a medical device?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 A. No, I have not.</p> <p>19 Q. (By Mr. Faes) In your practice, do you</p> <p>20 typically read the IFU for each mesh kit or device</p> <p>21 that you use before using it?</p> <p>22 A. Yes, I do.</p> <p>23 Q. You don't read -- do you -- you don't read</p> <p>24 the IFU every time you use the device. Correct? You</p>	<p style="text-align: center;">Page 109</p> <p>1 IFU is disclosing to you each of the risks and</p> <p>2 complications the company knew could occur with the</p> <p>3 kit or device that you're using?</p> <p>4 A. No, because I also take into consideration my</p> <p>5 surgical training and I know that there's some risks</p> <p>6 of surgery that aren't going to be -- aren't going to</p> <p>7 be included there, so I don't rely on the IFU to tell</p> <p>8 me all the risks.</p> <p>9 Q. Do you assume that when you read an IFU from</p> <p>10 a company regarding a mesh kit or medical device that</p> <p>11 the company is disclosing to you those complications</p> <p>12 and risks that could be significant for the patient</p> <p>13 and known to the company?</p> <p>14 A. Again, not necessarily because there's some</p> <p>15 that you just apply your surgical training to and you</p> <p>16 take that into consideration and assume that those are</p> <p>17 going to be some of the risks.</p> <p>18 Q. Do you assume that when you read an IFU for a</p> <p>19 medical device that the company was disclosing any</p> <p>20 risks and complications that would be inherent to the</p> <p>21 mesh material, so that you would know what those risks</p> <p>22 are?</p> <p>23 A. Yes, I would assume that they would -- they</p> <p>24 would include -- include those sorts of things</p>

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<p>1 specific to the device. 2 Q. Do you know whether or not -- strike that. 3 Do you know whether or not one of the 4 purposes of the IFU is to disclose each of the risks 5 and complications that can occur with the use of that 6 mesh kit in a woman's body?</p> <p>7 MR. GAGE: Object to form.</p> <p>8 A. I think it's to -- to communicate the risks, 9 but it's not meant to be comprehensive and I don't 10 think surgeons take it to be comprehensive either.</p> <p>11 Q. (By Mr. Faes) As you sit here today, do you 12 have an understanding of any standard whatsoever as to 13 what risks and complications are supposed to be 14 disclosed in an IFU?</p> <p>15 A. I believe there are some guidelines from the 16 FDA that help guide companies in what they should put 17 into the IFU.</p> <p>18 Q. Do you know what those guidelines are called? 19 A. No, I don't know what they're called.</p> <p>20 Q. Do you know if you've reviewed those 21 guidelines before?</p> <p>22 A. I have seen them before, yes.</p> <p>23 Q. Would you agree that your background and 24 experience is not necessarily the same as other</p>	<p>1 A. I think it would depend on what -- you 2 know -- what you're talking about, what sort of 3 situation you're talking about.</p> <p>4 Q. So you'd agree that it's possible that a -- 5 there could be a situation where a physician wouldn't 6 know about a potential risk or complication of the 7 Prosimax or Prolift that you did know about and that 8 doctor could still be a reasonable and prudent 9 physician and be doing his work within the standard of 10 care?</p> <p>11 MR. GAGE: Object to form.</p> <p>12 A. I think people have, you know, different 13 training in their residency, different experience, so 14 it's possible, but I think it's unlikely, because I 15 think any reasonable pelvic surgeon would be able to 16 anticipate the potential complications of pelvic -- 17 any pelvic surgery, whether it's with a kit or native 18 tissue or whatever technique that you're using.</p> <p>19 Q. (By Mr. Faes) So is -- 20 A. I don't think you would be surprised by 21 pelvic pain or be surprised by poor wound healing. 22 That should be anticipated.</p> <p>23 Q. So is it your testimony that if there was a 24 risk or complication of the Prosimax or Prolift device</p>
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<p>1 doctors who use medical devices or might consider 2 using the Prosimax?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 A. Well, of course, there's going to be a wide 5 range of doctors that might use medical devices. 6 There's going to be some that are very -- more 7 experienced than others.</p> <p>8 Q. (By Mr. Faes) You'd agree that you might 9 know about a complication from a particular mesh 10 device or kit from your own experience that another 11 doctor might not know about?</p> <p>12 A. I don't know if I would agree with that. I 13 think that if you're a pelvic surgeon, if you're -- 14 you're doing operations and you've been through 15 residency, then you would be aware of the potential 16 complications. You may not have experienced it. The 17 more surgery you do, the more you're bound to have 18 complications along the way, but you would be aware of 19 it.</p> <p>20 Q. So if you knew about a potential risk or 21 complication from the Prosimax or Prolift device that 22 another physician didn't know about, would you 23 consider that physician to not be a diligent and 24 reasonable physician for not knowing about that?</p>	<p>1 that a physician didn't know about, that that 2 physician wasn't reasonable and prudent, using your 3 words?</p> <p>4 A. I don't think I used those words, but . . . 5 Q. I think you said reasonable, so let me -- 6 A. Okay. 7 Q. -- let me strike that and I'll ask it again. 8 A. Okay. 9 Q. So is it your testimony that if there is a 10 risk or complication of the Prosimax or Prolift device 11 that an implanting physician didn't know about, that 12 that physician wasn't reasonable in his treatment and 13 care?</p> <p>14 MR. GAGE: Object to form.</p> <p>15 A. I would have to say that they're missing -- 16 they may be missing some knowledge or experience. 17 Q. (By Mr. Faes) Yeah. My question is actually 18 a little different than that. 19 A. Okay. 20 Q. My question isn't whether they -- whether 21 they're missing knowledge and experience. My question 22 is whether you consider them to not be reasonable in 23 their treatment and care of a physician -- of a 24 patient if there was a risk or complication of the</p>

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<p>1 Prosima or Prolift device that they didn't know about. 2 MR. GAGE: Object to form. 3 A. No, I disagree because they could still be 4 reasonable, they could still be giving the patient 5 good treatment and care even if they didn't know about 6 that risk or complication. 7 Q. (By Mr. Faes) In doing your work on this 8 case, have you ever been curious as to what the 9 regulatory affairs professionals department in 10 Ethicon, the professionals who are required to make 11 sure an IFU complies with FDA regulations, are you -- 12 have you been curious about what they thought needed 13 to be in an IFU? 14 MR. GAGE: Object to form. 15 A. Not really. 16 Q. (By Mr. Faes) That's not something that you 17 thought would be helpful in forming your opinions in 18 this case, that the Prosima and Prolift and Gynemesh 19 PS IFUs are adequate? 20 A. No, because I think they're adequate. I 21 think that they did adequately warn about potential 22 complications, so I think they did a fine job putting 23 it together. 24 Q. Would you agree with me that if Ethicon</p>	<p>1 and start over. 2 Do you agree that mesh shrinkage or 3 contraction can lead to severe pelvic pain? 4 A. No. 5 Q. Do you believe that wound contraction can 6 cause -- strike that. 7 Do you agree that wound contraction or scar 8 contraction around a mesh can lead to severe pelvic 9 pain? 10 A. Yes. 11 Q. Do you agree that -- strike that. 12 Do you agree that wound contraction or scar 13 contraction surrounding mesh can lead to painful 14 sexual intercourse? 15 A. (No response.) 16 Q. Do you want me to restate it since you can't 17 read it? 18 MR. GAGE: It's hard to read on the 19 screen here. 20 MR. FAES: Yeah. 21 A. Please. 22 Q. (By Mr. Faes) Do you agree that wound 23 contraction or scar contraction surrounding the mesh 24 can lead to painful sexual intercourse?</p>
<p style="text-align: center;">Page 115</p> <p>1 medical affairs knew that there was a potential risk 2 or complication attributable to the Gynemesh PS mesh, 3 itself, which, if occurred, could cause severe 4 permanent injury to a woman, that risk should be 5 disclosed in the IFU? Would you agree with that 6 statement? 7 A. No, because they're going to have multiple 8 discussions and opinions and bouncing things back and 9 forth and I think that what they put in the IFU is 10 perfectly adequate and reliable. 11 Q. Have you ever studied the question of what 12 risks and complications were known to doctors across 13 the country with various backgrounds and levels of 14 experience with regard to the use of the Prosima? 15 A. No, I have not studied that. 16 Q. Same question: Gynemesh PS? 17 A. No. 18 Q. Same question: Prolift? 19 A. No. 20 Q. Same question: Prolift Plus M? 21 A. No. 22 Q. I know you're not giving an opinion on, 23 but . . . Do you agree that -- well, actually, I think 24 I know your answer to this. I'm going to strike that</p>	<p style="text-align: center;">Page 117</p> <p>1 A. Yes. And it can also occur with wound 2 contraction without mesh. It occurs in native tissue 3 repairs, as well. 4 MR. FAES: Object and move to strike 5 after the answer "yes." 6 Q. (By Mr. Faes) Same question: Inability to 7 -- with regard to inability to engage in sexual 8 intercourse? 9 MR. GAGE: Object to form. 10 Q. (By Mr. Faes) Since he's going to object to 11 the form, I'll withdraw that and ask the whole 12 question. Would you agree that wound contraction or 13 scar contraction surrounding the mesh can lead to 14 inability to engage in sexual intercourse? 15 A. I don't think that there would be a case 16 where that would -- would occur, where they would be 17 unable to engage in sexual intercourse. 18 Q. But you did agree that it can cause painful 19 sexual intercourse? 20 A. Yes, pelvic -- pelvic surgery scarring can 21 cause painful intercourse. 22 Q. Would you agree that intercourse can be so 23 painful to where a person is unable to engage in 24 sexual intercourse?</p>

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<p>1 A. Uninterested, unwilling, but not unable.</p> <p>2 It's not as if the vagina is completely closed, but if 3 it's -- if you're saying because of pain, then, yes, 4 where they would be un -- unwilling, uninterested.</p> <p>5 Physically, they would be able to have intercourse, 6 but it would be too painful.</p> <p>7 Q. So you make a distinction between someone who 8 is unable to have sexual intercourse because it's too 9 painful versus someone who is just physically unable 10 to have intercourse?</p> <p>11 A. Well, yes. I mean, there are -- especially 12 with native tissue repairs, there are situations where 13 the vagina is so scared and contracted where they are 14 physically unable to have intercourse, not just 15 because of pain, because they -- their vagina is 16 absolutely too small.</p> <p>17 Q. Okay. So you're --</p> <p>18 A. And I don't --</p> <p>19 Q. -- you're making a distinction, not to be 20 indelicate, but between someone who is physically 21 unable to be penetrated and someone who --</p> <p>22 A. Has --</p> <p>23 Q. -- prefers not to be because it's too 24 painful.</p>	<p>1 A. Yes, as in all pelvic surgery.</p> <p>2 Q. Would you agree that one of the risks of the 3 pelvic organ prolapse products is that they can lead 4 to dyspareunia?</p> <p>5 A. Yes, as in all pelvic surgery.</p> <p>6 MR. FAES: Move to strike after the 7 answer "yes."</p> <p>8 Q. (By Mr. Faes) Would you agree that one of 9 the risks of the pelvic organ prolapse products is 10 that they can lead to multiple surgical interventions 11 to treat the complications?</p> <p>12 A. Yes, that can occur.</p> <p>13 Q. Would you agree that one of the risks of the 14 pelvic organ prolapse products is that a woman can 15 sustain life-changing complications as a result of 16 those products?</p> <p>17 A. Yes, that can occur.</p> <p>18 Q. Would you agree that one of the risks of the 19 pelvic organ prolapse products is erosions at multiple 20 sites?</p> <p>21 A. Yes.</p> <p>22 Q. Would you agree that with the pelvic organ 23 prolapse products, most women who have erosions or 24 extrusions require surgical intervention?</p>
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<p>1 A. Right.</p> <p>2 Q. Is that right?</p> <p>3 A. Yes.</p> <p>4 Q. Would you agree that one of the risks of the 5 -- I'm going to strike that and ask if we can agree 6 to something, so I don't have to re-ask these 7 questions three different times. For the purposes 8 of these questions, as we discussed earlier, when 9 I refer to the pelvic organ prolapse products, 10 I'm referring to the Prolift, the Prosimax and the 11 Gynemesh PS, which are the three products that you're 12 offering an opinion on. If you can't answer the 13 question the same way for all three products, let me 14 know and then I'll have to go through each three 15 separately. Can we agree to that?</p> <p>16 A. Yes.</p> <p>17 Q. Would you agree that one of the risks of the 18 pelvic organ prolapse products is that they can lead 19 to complex mesh erosions?</p> <p>20 MR. GAGE: Object to form.</p> <p>21 A. Yes, that is a risk.</p> <p>22 Q. (By Mr. Faes) Would you agree that one of 23 the risks with the pelvic organ prolapse products is 24 that they can lead to chronic pain syndrome?</p>	<p>1 A. Yes.</p> <p>2 Q. Would you agree that with the Pros -- or 3 strike that.</p> <p>4 Would you agree that with the pelvic organ 5 prolapse products multiple attempts to excise the mesh 6 may be required?</p> <p>7 A. Yes.</p> <p>8 Q. Would you agree with the pelvic organ 9 prolapse that one of the risks is life-changing 10 complications?</p> <p>11 MR. GAGE: Object to form.</p> <p>12 A. Yes.</p> <p>13 Q. (By Mr. Faes) Would you agree that one of 14 the risks of the pelvic organ prolapse products is 15 incapacitating pelvic pain?</p> <p>16 A. Yes, as in all pelvic surgery.</p> <p>17 MR. FAES: Move to strike after the 18 answer "yes."</p> <p>19 Q. (By Mr. Faes) Would you agree that one of 20 the risks of the pelvic organ prolapse products is 21 large scale erosions that are not easy to resolve?</p> <p>22 A. There's a very remote risk.</p> <p>23 Q. But is the answer yes?</p> <p>24 A. Yes.</p>

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<p>1 Q. It is risk. The list of complications and 2 risks that I just asked you about, do you know whether 3 or not Ethicon knew about all those risks on the day 4 the pelvic organ prolapse products first went on the 5 market?</p> <p>6 A. I can't recall.</p> <p>7 Q. So you don't know, one way or the other, 8 sitting here today?</p> <p>9 A. I don't -- yes, I don't know.</p> <p>10 Q. If they did know, do you agree that those 11 risks should have been in the IFU?</p> <p>12 A. I think those are risks that pelvic surgeons 13 would anticipate, because as I stated, most of those 14 risks, with the exception of the erosion, are risks of 15 pelvic surgery.</p> <p>16 Q. Okay. I didn't ask about whether they were 17 risks that pelvic surgeons would anticipate. My 18 question was very specific. My question was: If 19 Ethicon did know about those risks, do you agree that 20 those risks should have been put in the IFU?</p> <p>21 MR. GAGE: Object to form.</p> <p>22 A. I don't think they needed to be in the IFU, 23 because the surgeons with their knowledge and being 24 professionals would be able to anticipate that.</p>	<p>1 MR. FAES: Yeah, I think -- yeah, yeah, 2 yeah, yeah. That's fine.</p> <p>3 MR. GAGE: Because you might be entitled 4 to a few more minutes. I don't know.</p> <p>5 MR. FAES: Yeah, I think ten. 6 Anyway . . .</p> <p>7 Q. (By Mr. Faes) Would you agree with the way 8 -- strike that.</p> <p>9 Would you agree that compared to the way the 10 mesh was used before the Prolift, the Prolift provided 11 for more mesh to be put in a woman's pelvis than had 12 been previously used?</p> <p>13 MR. GAGE: Object to form.</p> <p>14 A. I think it depended on how that surgeon was 15 configuring the Gynemesh supplementation, so it could 16 be the same, it could be more, it could be less.</p> <p>17 Q. (By Mr. Faes) Do you believe that there is a 18 sheet of Gynemesh PS flat mesh available as a single 19 sheet that is more area than the mesh in the entire 20 Prolift kit?</p> <p>21 A. Oh, in the Total Prolift?</p> <p>22 Q. Yes.</p> <p>23 A. No. I think the Total Prolift is probably 24 more. I'm thinking about one compartment at a time.</p>
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<p>1 MR. FAES: Move to strike after the word 2 "IFU."</p> <p>3 Q. (By Mr. Faes) And that's your opinion for 4 all of the risks that we just went through today?</p> <p>5 A. Yes.</p> <p>6 Q. When the Prosima first came onto the market, 7 surgeons were not experienced on any long-term basis 8 with implanting mesh with a vaginal support device. 9 Correct?</p> <p>10 A. That's correct.</p> <p>11 Q. Do you know the area of the -- do you know 12 the square area of the mesh used in the Prosima kits?</p> <p>13 A. Not off the top of my head, no.</p> <p>14 MR. GAGE: Object. Form.</p> <p>15 Q. (By Mr. Faes) And I think you've already 16 answered this question: You don't know what sizes and 17 configurations the Gynemesh PS mesh is offered in. 18 Correct?</p> <p>19 A. That's correct.</p> <p>20 MR. GAGE: I show about eight minutes 21 before she needs to go.</p> <p>22 MR. FAES: Okay.</p> <p>23 MR. GAGE: And we can sort out at 4:20 24 how much -- did you get three hours in, did you not.</p>	<p>1 I think if you combine -- you -- you know -- combined 2 an anterior and posterior Gynemesh, it would probably 3 be more than a Prolift, Total Prolift.</p> <p>4 Q. Okay. What about just one Prolift, just the 5 anterior or just the posterior, do you believe that 6 there's a sheet of Gynemesh PS that's available that 7 would be more mesh, in terms of total square area than 8 either the anterior Prolift with the arms included or 9 the posterior Prolift with the arms included?</p> <p>10 A. Yeah. I think it would probably be very 11 similar once you added it together. And whenever you 12 do a Prolift, you usually trim a lot of the mesh --</p> <p>13 Q. What --</p> <p>14 A. -- on the tail or on the sides.</p> <p>15 Q. What size Gynemesh PS would that be that 16 would greater than the Prolift?</p> <p>17 A. I mean, I think one size was, I think, ten by 18 ten centimeters, if I remember correctly. And so it 19 just depends on how the surgeon fashioned it. So it 20 could be more, it could be less.</p> <p>21 Q. Do you know if there's more mesh in an 22 anterior or posterior Prolift than what would be 23 contained in a ten by ten centimeter strip of Gynemesh 24 PS?</p>

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<p>1 A. It's less, the anterior Prolift? The 2 anterior Prolift is bigger than a posterior, yeah. 3 Q. What do you believe the area of the posterior 4 Prolift is? 5 A. I don't know off the top of my head. I mean, 6 I'm just picturing it from having used it. It's not 7 ten by ten centimeters. 8 Q. So you don't -- 9 A. It's much less than that, even if you add the 10 arms. 11 Q. You don't know the total area with the arms, 12 but you -- but you believe it's less than ten by ten 13 centimeters? 14 A. Absolutely. 15 Q. You believe it's less than a hundred square 16 centimeters? 17 A. Absolutely. 18 Q. Is the same -- is the answer -- 19 A. Because you trim it. You don't use the whole 20 thing. And you trim the arms. 21 Q. Do you know if when physicians use a 22 ten-by-ten sheet of Gynemesh PS, whether or not they 23 typically trim it or typically use the entire square 24 of mesh?</p>	<p>1 depended on how that surgeon used the Gynemesh. So if 2 they're using a Total Prolift, they would have 3 potentially used two Gynemesh grafts on that same 4 woman previously, so it could still be the same, more 5 or less, depending on how they cut their Gynemesh and 6 how they utilize it. 7 Q. Okay. Let me ask you this question -- 8 A. Okay. 9 Q. -- would you agree that compared with the way 10 mesh was used for the repair of pelvic organ prolapse 11 before the transvaginal mesh technique with the 12 Gynemesh Prolene Soft, the Prolene Soft provided for 13 more mesh -- strike that. 14 Would you agree with me that compared with 15 the way mesh was used for the repair of pelvic organ 16 prolapse before the transvaginal mesh technique using 17 the Gynemesh Prolene Soft was developed, the 18 transvaginal technique with Gynemesh Prolene Soft 19 provided for more mesh to be put in a woman's pelvis 20 than had been previously used for pelvic organ 21 prolapse repair? 22 MR. GAGE: Object to form. 23 A. I can't really answer that, because there was 24 no standardized way to do that surgery before.</p>
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<p>1 A. They typically trim it. That's what I said 2 earlier, it could be the same, it could be more, it 3 could be less. 4 Q. So you disagree that, compared with the way 5 the mesh was typically used before the Prolift, the 6 Prolift provides for more mesh to be put in a woman's 7 pelvis than had been previously used before Prolift 8 kits were available? 9 MR. GAGE: Object to form. 10 A. Correct, I disagree with that. 11 Q. (By Mr. Faes) But only with -- only if just 12 the anterior or posterior is used by itself? 13 A. Well, if -- okay. If you -- yeah, comparing 14 one compartment to one Gynemesh graft, yeah, comparing 15 one. But if you did a Gynemesh graft in each 16 compartment -- 17 Q. Right. So -- 18 A. -- that would be the comparison. I wouldn't 19 compare one Gynemesh graft to a Total Prolift. 20 Q. So would you agree that, compared to the way 21 the mesh was used before the Total Prolift, the Total 22 Prolift provided for more mesh to be put in a woman's 23 pelvis than had generally previously been used? 24 A. I feel like we're going in circles. It just</p>	<p>1 Q. (By Mr. Faes) So is the answer to my 2 question you can't -- you can't answer one way or 3 another, you just don't know? 4 A. It's a question that cannot be answered 5 because it was not a standardized technique. 6 Q. If Ethicon medical affairs believed that a 7 caution needed to be taken by a doctor before using 8 Prosima in a particular class of women, should that 9 have been put in the IFU? 10 A. I would say yes to that. 11 Q. If Ethicon -- I think I'll ask two more 12 questions and then you probably gotta get out of here. 13 Right? Okay. Unless you need to get out of here 14 right now. Two more questions -- 15 MR. GAGE: The real clock is faster than 16 my watch yes. 17 MR. FAES: Okay. 18 MR. GAGE: Yeah. 19 Q. (By Mr. Faes) If Ethicon medical affairs 20 believed that a caution should be used before putting 21 a Prosima into a woman based on some fact about her 22 demographics or her age or her level of prolapse or 23 comorbidities or anything that was specific that could 24 be related to specific patients, should that</p>

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<p>1 information have been in the IFU, so that doctors 2 would have that information when deciding to do with 3 their patients?</p> <p>4 MR. GAGE: Object to form.</p> <p>5 A. I don't --</p> <p>6 Q. (By Mr. Faes) Deciding -- I think I 7 flubbed the end of that question. I meant to say 8 deciding what to do with their patients. I don't 9 know if the realtime is wrong or I'm wrong, but do you 10 want me to answer the -- re-ask the question? It's a 11 long one.</p> <p>12 A. Please.</p> <p>13 Q. We'll make this the last question then.</p> <p>14 A. Yeah.</p> <p>15 Q. If Ethicon medical affairs believed that a 16 caution should be used before putting a Prosima into a 17 woman based on some fact about her demographics or her 18 age or her level of prolapse or comorbidities or 19 anything like that was specific that could be related 20 to specific patients, should that information 21 have been in the IFU, so doctors would have 22 that information when deciding what to do with 23 their patients?</p> <p>24 MR. GAGE: Object to form.</p>	<p>1 A. Not necessarily. 2 Q. (By Mr. Faes) You say not necessarily. Are 3 there --</p> <p>4 A. Uh-huh. 5 Q. -- are there situations where you believe it 6 would be appropriate to not include a warning or 7 precaution that medical affairs thought should be in 8 the IFU for marketing reasons?</p> <p>9 MR. GAGE: Object to form.</p> <p>10 A. It depends on -- it depends on what it was. 11 You know, when they're coming up with these things, 12 they're taking in numerous considerations, so it would 13 -- it would just depend on what it was. It would -- 14 it would give me some pause if that was the only 15 reason for marketing reasons, but I would have to know 16 more specifics before I drew a conclusion about it.</p> <p>17 Q. (By Mr. Faes) So if medical affairs said, I 18 think this warning or precaution is really important 19 and marketing comes in and says, yeah, but it's going 20 to hurt the sales of our product, so we're not going 21 to put it in, you believe that there are situations 22 where that would not be wrongful?</p> <p>23 MR. GAGE: Object to form.</p> <p>24 A. Right, because as I've said before, there's</p>
<p style="text-align: center;">Page 131</p> <p>1 A. Again, it goes back to, what do you need to 2 put in the IFU, because that's why we're physicians. 3 We're professionals. We're trained to make these 4 judgment calls. I mean, I think it -- I think that 5 the IFU is perfectly adequate. I don't think anything 6 was left out, so I can't think of what they would come 7 up with that would change that opinion that I would 8 say -- I would say no to that question, because, 9 again, they're going to be discussing things back and 10 forth and bouncing ideas off of each other. That 11 doesn't all need to go into the IFU.</p> <p>12 Q. (By Mr. Faes) But if Ethicon medical affairs 13 believed that that caution should be put in there, you 14 believe that that information doesn't need to be 15 included, even if Ethicon medical affairs believes 16 it needs to be put in there?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 A. As I already answered, I would say no.</p> <p>19 Q. (By Mr. Faes) If Ethicon medical affairs 20 believed that a particular warning or caution should 21 be added to the IFU, but that caution or warning 22 wasn't added due to marketing reasons, would you agree 23 that that would be wrongful?</p> <p>24 MR. GAGE: Object to form.</p>	<p style="text-align: center;">Page 133</p> <p>1 some risks that are not in an IFU for any product that 2 surgeons are aware of, like death. Death is a risk of 3 any surgical device with surgery. You know, surgery 4 has a risk of death, so they may not want to put that 5 in there for marketing reasons.</p> <p>6 Q. (By Mr. Faes) So you believe that there are 7 situations where it's appropriate for marketing to 8 override the judgment of medical affairs?</p> <p>9 MR. GAGE: Object to form.</p> <p>10 A. I don't -- I don't -- I don't want to agree 11 with that. I mean, I don't want to disagree with that 12 because medical affairs should be the priority, but 13 there are so many considerations that go into it.</p> <p>14 MR. FAES: I'll object and move to 15 strike after the word "priority." And Doctor, I'll 16 let you go, because --</p> <p>17 THE WITNESS: Okay.</p> <p>18 MR. FAES: -- I'm sorry. I asked way 19 more questions than I intended to. We got into a --</p> <p>20 THE WITNESS: I know. We were on a roll 21 there.</p> <p>22 MR. FAES: We got into a thing there.</p> <p>23 THE WITNESS: Yeah.</p> <p>24 MR. GAGE: All right. So we're off the</p>

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<p style="text-align: center;">Page 134</p> <p>1 record now. 2 (Deposition concluded at 4:25 p.m.) 3 (Signature reserved.) 4 * * * * *</p> <p>5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>	<p style="text-align: center;">Page 136</p> <p>1 ACKNOWLEDGMENT OF DEPONENT 2 3 I, _____, do 4 hereby certify that I have read the 5 foregoing pages, and that the same is 6 a correct transcription of the answers 7 given by me to the questions therein 8 propounded, except for the corrections or 9 changes in form or substance, if any, 10 noted in the attached Errata Sheet. 11 12 13 14 CHRISTINA PRAMUDJI, M.D. DATE 15 16 17 Subscribed and sworn 18 to before me this 19 ____ day of _____, 20____. 20 My commission expires: _____ 21 22 23 Notary Public 24</p>
<p style="text-align: center;">Page 135</p> <p>1 - - - - - 2 E R R A T A 3 - - - - -</p> <p>5 PAGE LINE CHANGE</p> <p>7 REASON: _____ 8 _____ 9 REASON: _____ 10 _____ 11 REASON: _____ 12 _____ 13 REASON: _____ 14 _____ 15 REASON: _____ 16 _____ 17 REASON: _____ 18 _____ 19 REASON: _____ 20 _____ 21 REASON: _____ 22 _____ 23 REASON: _____ 24 _____</p>	<p style="text-align: center;">Page 137</p> <p>1 THE STATE OF TEXAS: 2 COUNTY OF FT. BEND: 3 I, Tamara Vinson, a Certified Shorthand 4 Reporter and Notary Public in and for the State of 5 Texas, do hereby certify that the facts as stated by 6 me in the caption hereto are true; that the above and 7 foregoing answers of the witness, CHRISTINA PRAMUDJI, 8 M.D., to the interrogatories as indicated were made 9 before me by the said witness after being first duly 10 sworn to testify the truth, and same were reduced to 11 typewriting under my direction; that the above and 12 foregoing deposition as set forth in typewriting is a 13 full, true, and correct transcript of the proceedings 14 had at the time of taking of said deposition. 15 I further certify that I am not, in any 16 capacity, a regular employee of the party in whose 17 behalf this deposition is taken, nor in the regular 18 employ of his attorney; and I certify that I am not 19 interested in the cause, nor of kin or counsel to 20 either of the parties. 21 GIVEN UNDER MY HAND AND SEAL OF OFFICE, on 22 this, the ____ day of March, 2016. 23 24</p> <p style="text-align: right;">_____ 19 Tamara Vinson, Texas CSR No. 3015 20 Expiration Date: 12-31-2016</p> <p>21 GOLKOW TECHNOLOGIES, INC. 22 Texas CRCB Registration #690 23 440 Louisiana, Suite 910 24 Houston, Texas 77002 www.golkow.com</p>

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